IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler Hon. Joel Schneider **JURY TRIAL DEMANDED**

CONSOLIDATED AMENDED MEDICAL MONITORING CLASS ACTION COMPLAINT

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The Medical Monitoring Class Plaintiffs ("Plaintiffs"), who file this Consolidated Amended Medical Monitoring Class Action Complaint ("Master Class Complaint")[1] against the below-enumerated Defendants.

I. INTRODUCTION

1. Plaintiffs bring this action on behalf of themselves and all others who consumed Defendants' generic valsartan-containing drugs ("VCDs")[2] that were contaminated with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA"), and/or an IARC- and EPA-listed probable human carcinogen known as N-nitrosodiethylamine ("NDEA"), in the United States, and who thus suffered cellular damage, genetic harm, and/or are at an increased risk of developing cancer as a result, but have not yet been diagnosed with cancer. Plaintiffs seek injunctive and monetary relief, including creation of a fund to finance independent medical monitoring services, including but not limited to notification to all people exposed to this contamination, examinations, testing, preventative screening, and care and treatment of cancer resulting, at least in part, from the exposure to the NDMA or NDEA contamination.

[1] This is one of three master complaints being filed in this multi-district litigation. The filing of three master complaints is to streamline the pleadings and issues for the parties' mutual convenience only. Class Plaintiffs do not waive any claims that are not raised herein, or that are asserted in another master complaint.

[2] All of the various acronyms used throughout this complaint are summarized in the glossary attached as Exhibit A hereto.

2. Valsartan and its combination therapy with hydrochlorothiazide are the generic versions of the registered listed drugs ("RLDs") Diovan® ("DIOVAN") and Diovan HCT® ("DIOVAN HCT"), respectively. Amlodipine-valsartan and its combination therapy with hydrochlorothizide are the generic versions of the RLDs of Exforge® ("EXFORGE") and Exforge HCT® ("EXFORGE HCT"), respectively. These RLDs are indicated for, among other things, the treatment of high blood pressure, a condition affecting approximately 103 million Americans according to the American Heart Association.[3] Several million U.S. patients pay for (in whole or in part) and consume generic valsartan each year.

3. At all times during the period alleged herein, Defendants represented and warranted to consumers that their VCDs were therapeutically equivalent to and otherwise the same as their RLDs, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

4. According to the Food and Drug Administration's ("FDA") testing, Defendants' generic VCDs contained NDMA and/or NDEA contamination levels

[3] American Heart Association News, More than 100 million Americans have high blood pressure, AHA says, Heart.org (Jan. 31, 2018), https://www.heart.org/en/news/2018/05/01/more-than-100-million-americans-have-high-blood-pressure-aha-says.

that were in some cases hundreds of times higher than the FDA's February 28, 2019 updated interim limits for NDMA and/or NDEA impurities. The FDA has yet to release testing results for other impurities such as N-Nitroso-N-methyl-4-aminobutyric acid ("NMBA").

5. The contamination of Defendants' VCDs began in or around 2011 when Defendants changed the manufacturing process to include a solvent suspected of producing NDMA, NDEA, and potentially other contaminants. Defendants had actual and constructive notice of the contamination as early as 2011.

6. Defendants have been illegally manufacturing, selling, labeling, marketing, and distributing the misbranded and/or adulterated VCDs in the United States since as far back as September 2012, when Defendant Mylan launched a DIOVAN HCT generic after its valsartan HCT Abbreviated New Drug Application ("ANDA") was approved by the FDA.

7. For years, Defendants willfully ignored warnings signs regarding the operating standards at several of the overseas manufacturing plants where Defendants' generic VCDs were manufactured for import to the United States, and knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed contaminated, adulterated, and/or misbranded VCDs for consumption in the United States.

8. Plaintiffs thus consumed Defendants' VCDs that were illegally introduced into the market by Defendants, exposing Plaintiffs to highly dangerous and potentially fatal carcinogenic substances. Defendants' conduct requires medical monitoring and constitutes negligence, defective manufacture, failure to warn, a violation of the Magnuson-Moss Warranty Act, breach of implied warranty of merchantability, breach of express warranty, fraudulent concealment, and other legal violations as set forth herein.

II. PARTIES

A. Class Representatives

9. The Master Complaints in this MDL are divided among Personal Injury, Medical Monitoring, and Economic Reimbursement for administrative purposes, as noted in Footnote 1. The below-identified Medical Monitoring Plaintiffs are absent class members in the Economic Reimbursement Class, and do not waive their status as absent class members by dint of serving as proposed Class Representatives for the medical monitoring class or classes. Furthermore, the parties below identified as Medical Monitoring Plaintiffs, in filing this Complaint, which is limited to medical monitoring per the administrative structure, do not waive, forego, or otherwise relinquish any entitlement they have to economic remedies for all harms alleged. Plaintiffs preserve their entitlement to any economic remedy for all harms alleged.

10. Plaintiff John Judson is a resident of the State of California. He was prescribed and used Valsartan from approximately 2014 to 2018, at a dose of 320 mg per day. The distributors of Plaintiff's Valsartan were Camber, Hetero USA, Hetero Labs, and Hetero, Solco, Prinston, Huahai US, and ZHP, as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

11. Plaintiff Sarah Zehr is a resident of the State of Florida. She was prescribed and used Valsartan from approximately May 2016 until November 2018, at a dose of 160 mg. The distributors of Plaintiff's Valsartan were Solco, Prinston, Huahai US, and ZHP, as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

12. Plaintiff Robert Kruk is a resident of the State of Illinois. He was prescribed and used Valsartan for approximately eight years, at a dose of 160 mg. The distributors of Plaintiff's Valsartan were Solco, Prinston, Huahai US, ZHP and Walmart, as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer.

13. Plaintiff Michael Rives is a resident of the State of Illinois. He was prescribed and used Valsartan from approximately 2014 until 2018, at a dose of 100 mg. The distributors of Plaintiff's Valsartan were Aurobindo USA, Aurolife, Aurobindo, Actavis, Teva, Solco, Prinston, Huahai US, and ZHP, as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer.

14. Plaintiff Robert Fields is a resident of the State of Maryland. He was prescribed and used Valsartan from approximately 2014 until 2018, at a dose of 320 mg per day. The distributors of Plaintiff's Valsartan were Actavis, Teva, Huahai US, and ZHP as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer.

15. Plaintiff Celestine Daring is a resident of the State of Maryland. She was prescribed and used Valsartan from approximately 2007 until 2018, at a dose of 320 mg per day. The distributors of Plaintiff's Valsartan were and Mylan Pharmaceuticals, Mylan Laboratories, Mylan, Aurobindo USA, Aurolife, and Aurobindo, as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer.

16. Plaintiff Paulette Silberman is a resident of the State of New Jersey. She was prescribed and used Valsartan from approximately July 2017 to June 2018, at a dose of 160 mg. The distributors of Plaintiff's Valsartan were Solco, Prinston, Huahai US, ZHP, Aurobindo USA, Aurolife, Aurobindo, and CVS, as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

17. Plaintiff Valerie Rodich-Annese is a resident of the State of Pennsylvania. She was prescribed and used Valsartan from approximately January 2016 until July 2018, at doses of 160 mg and 320 mg per day. The distributors of Plaintiff's Valsartan were Aurobindo USA, Aurolife, Aurobindo, Solco, Prinston, Huahai US, and ZHP as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

18. Plaintiff Roger Tasker is a resident of the State of West Virginia. He was prescribed and used Valsartan from approximately 2014 through 2017, at a dose starting at 40 mg and ultimately 320 mg per day. The distributors of Plaintiff's Valsartan were Mylan Pharmaceuticals, Mylan Laboratories, Mylan, Solco, Prinston, Huahai US, and ZHP, as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered

cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

19. Plaintiff Judy Tasker is a resident of the State of West Virginia. She was prescribed and used Valsartan from approximately 2016 through 2018, at a dose of 40 mg per day. The distributors of Plaintiff's Valsartan were Mylan Pharmaceuticals, Mylan Laboratories, Mylan, Solco, Prinston, Huahai US, and ZHP, as defined below. This Valsartan was contaminated with NDMA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

B. The Active Pharmaceutical Ingredient Manufacturer Defendants

20. For ease of reading, this Master Complaint generally organizes Defendants by the distribution level at which they principally operate. The following Defendants manufacture the active pharmaceutical ingredient ("API") for Defendants' VCDs, or are closely affiliated with an entity that does so. The inclusion of certain Defendants in this section does not mean they are not properly classifiable as another type of defendant, or vice versa (e.g., a Defendant listed in this subsection may also be a distributor; a Defendant listed in the distributor subsection may also be an API manufacturer).

1. Zhejiang Huahai Pharmaceutical Co., Ltd. Entities

21. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") is a Chinese corporation, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. The company also has a United States headquarters located at 2009 and 2002 Eastpark Blvd., Cranbury, NJ 08512. ZHP on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this action, ZHP has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic VCDs throughout the United States.

22. Defendant Huahai US Inc. ("Huahai US") is a New Jersey corporation, with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Huahai US is the wholly-owned subsidiary of ZHP. Huahai US "focus[es] on the sales and marketing of [ZHP's] APIs and Intermediates."[4] At all times material to this case, Huahai US has been engaged in the manufacture, sale, and distribution of contaminated, adulterated, and/or misbranded generic VCDs in the United States.

23. Defendant Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC ("Prinston") is a Delaware corporation with its principal place of business located

[4] Huahai US, Homepage, https://www.huahaius.com/index.html (last visited Apr. 5, 2019).

at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Defendant Prinston is a majority-owned subsidiary of ZHP. At all times material to this case, Prinston has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic VCDs in the United States.

24. Defendant Solco Healthcare US, LLC ("Solco") is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Solco is a wholly-owned subsidiary of Prinston and ZHP. At all times material to this case, Solco has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic VCDs in the United States.

25. Collectively, ZHP, Huahai US, Prinston, and Solco will be referred to as the ZHP Defendants. Much of the VCDs manufactured by the ZHP Defendants contains NDMA levels ***hundreds of times*** higher than acceptable limits for human consumption, according to laboratory results published by the FDA.[5] Some of its VCDs also contained NDEA.[6]

26. The ZHP Defendants also manufactured valsartan-containing API for the following other finished-dose manufacturers: Defendants Teva Pharmaceutical

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[5] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products (last visited June 13, 2019).

[6] Torrent has only recalled VCDs by ZHP.

Industries Ltd., Teva Pharmaceuticals USA, Inc., and Torrent Pharmaceuticals, Ltd.

27. In turn, the finished-dose manufacturer defendants' VCDs have unique labelers/distributors, as well as repackagers.

2. Hetero Labs, Ltd. Entities

28. Defendant Hetero Labs, Ltd. ("Hetero Labs") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Telangana, India. Hetero Labs on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this action, Hetero Labs has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic VCDs throughout the United States.

29. Defendant Hetero Drugs, Limited ("Hetero") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Telangana, India. "Hetero has a strong established global presence with 36 manufacturing facilities and a robust network of business partners and marketing offices strategically located across the world."[7] Hetero on its own and/or through its subsidiaries regularly conducts business in

[7] Hetero, GLOBAL FOOTPRINT, https://www.heteroworld.com/global-footprint.php (last visited June 6, 2019).

New Jersey and throughout the United States and its territories and possessions. Hetero Labs is the wholly-owned subsidiary of Hetero. At all times material to this action, Hetero has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic VCDs throughout the United States.

30. Defendant Hetero USA Inc. ("Hetero USA") is "the US representation of HETERO, a privately owned; researched based global pharmaceutical company."[8] Hetero USA is a Delaware corporation with its principal place of business located at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Hetero USA is the wholly-owned subsidiary of Hetero. At all times material to this action, Hetero USA has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic VCDs throughout the United States.

31. Defendant Camber Pharmaceuticals, Inc. ("Camber") is a Delaware corporation, with its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. Camber is the wholly owned subsidiary of Hetero Drugs. At all times material to this action, Camber has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, misbranded, and/or unapproved VCDs throughout the United States.

[8] Hetero USA, LINKEDIN, https://www.linkedin.com/company/hetero-usa-inc/about/ (last visited June 5, 2019).

32. Collectively, Hetero Labs, Hetero, Hetero USA, and Camber will be referred to as the Hetero Defendants in this Complaint.

33. The valsartan-containing API manufactured by Hetero was distributed to Hetero's U.S. subsidiaries or affiliates including Hetero USA and Camber. In turn, Camber supplied Hetero-manufactured valsartan API to at least three repackagers, including AvKARE, Inc., RemedyRepack, Inc., and Preferred Pharmaceuticals.

3. Mylan Laboratories, Ltd. Entities

34. Defendant Mylan Laboratories, Ltd. ("Mylan Laboratories") is a foreign corporation, with its principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Mylan Laboratories on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this action, Mylan Laboratories has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic VCDs throughout the United States.

35. Defendant Mylan N.V. ("Mylan") is a global generic and specialty pharmaceuticals company registered in the Netherlands, with principal executive offices in Hatfield, Hertfordshire, UK and a Global Center in Canonsburg, Pennsylvania. According to Mylan's website: "The Chief Executive Officer and other executive officers of Mylan carry out the day-to-day conduct of Mylan's

worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania." Mylan Laboratories is a wholly owned subsidiary of Mylan. At all times material to this action. Mylan on its own and/or through its subsidiaries regularly conducted business and throughout the United States and its territories and possessions. Mylan has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic VCDs throughout the United States.

36. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a West Virginia corporation, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan Pharmaceuticals is the registered holder of Mylan Laboratories' ANDA for its VCDs. At all times material to this action, Mylan Pharmaceuticals has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic VCDs throughout the United States.

37. Collectively, Mylan Laboratories, Mylan, and Mylan Pharmaceuticals will be referred to as the Mylan Defendants in this Complaint.

38. The Mylan Defendants' valsartan-containing API was supplied in large part to itself due to Mylan's vertically integrated supply chain. According to Mylan's website, "[b]eing a manufacturer of API makes Mylan one of the few global generics companies with a comprehensive, vertically integrated supply

chain" that Mylan touts as "provid[ing] us with an extra measure in the quality process that we can own[.]"[9]

39. Some of the Mylan Defendants' valsartan-containing API was also supplied to Defendant Teva Pharmaceuticals USA, Inc., which is named and identified below.

4. Aurobindo Pharma, Ltd. Entities

40. Defendant Aurobindo Pharma, Ltd. ("Aurobindo") is a foreign corporation with its principal place of business at Plot no. 2, Maitrivihar, Ameerpet, Hyderabad-500038 Telangana, India, and a United States headquarters at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Aurobindo has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded VCDs in the United States.

41. Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a Delaware corporation with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. It is a wholly-owned subsidiary of Aurobindo. At all times material to this case, Aurobindo USA has

[9] Mylan, ACTIVE PHARMACEUTICAL INGREDIENTS, https://www.mylan.com/en/products/active-pharmaceutical-ingredients (last visited June 6, 2019).

been engaged in the manufacturing, sale, and distribution of contaminated VCDs in the United States.

42. Defendant Aurolife Pharma, LLC ("Aurolife") is a Delaware limited liability company with its principal place of business at 2400 US- 130, North, Dayton, New Jersey 08810. It is a wholly-owned subsidiary of Aurobindo USA. At all times material to this case, Aurolife has been engaged in the manufacturing, sale, and distribution of contaminated VCDs in the United States.

43. Aurobindo, Aurobindo USA, and Aurolife are collectively referred to as the Aurobindo Defendants in this Complaint.

44. Aurobindo's valsartan-containing API was supplied in large part to itself due to its vertically integrated supply chain. "Aurobindo adds value through superior customer service in the distribution of a broad line of generic pharmaceuticals, leveraging vertical integration and efficient controlled processes."[10]

C. The Finished-Dose Defendants[11]

1. The Teva Defendants

45. Defendant Teva Pharmaceutical Industries Ltd. ("Teva") is a foreign company incorporated and headquartered in Petah Tikvah, Israel. Teva on its own

[10] Aurobindo USA, OUR STORY, https://www.aurobindousa.com/company/our-story/ (last visited June 5, 2019).

[11] The ZHP, Hetero, Mylan, and Aurobindo Defendants also qualify as finished

and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic VCDs in the United States.

46. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is a wholly owned subsidiary of Teva. At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic VCDs in the United States.

47. Actavis, LLC ("Actavis") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva's wholly owned subsidiary. At all times material to this case, Actavis has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

48. Arrow Pharm Malta Ltd. ("Arrow") is a foreign corporation headquartered at HF62 HalFar Industrial Estate, HalFar, BBG 300, Malta. Teva owns the entirety of Arrow, which on its own and/or through its parent company and subsidiaries regularly conducts business throughout the United States of

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dose Defendants, but the party allegations are listed above.

America and its territories and possessions. At all times material to this case, Arrow has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded VCDs in the United States.

49. Actavis Pharma, Inc. ("Actavis Pharma") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva's wholly owned subsidiary. At all times material to this case, Actavis Pharma has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded VCDs in the United States.

50. Teva, Teva USA, Arrow, Actavis and Actavis Pharma are collectively referred to as the Teva Defendants in this Complaint.

2. The Torrent Defendants

51. Defendant Torrent Private Limited ("Torrent") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Torrent on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Torrent has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded VCDs in the United States.

52. Defendant Torrent Pharmaceuticals, Ltd. ("Torrent Pharmaceuticals") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Over seventy percent of Torrent Pharmaceuticals is owned by Torrent. Torrent Pharmaceuticals on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Torrent Pharmaceuticals has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded VCDs in the United States.

53. Defendant Torrent Pharma, Inc. ("Torrent Pharma") is a Delaware corporation with its principal place of business at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. It is a wholly-owned subsidiary of Torrent Pharmaceuticals. At all times material to this case, Torrent Pharma has been engaged in the manufacturing, sale, and distribution of contaminated VCDs in the United States.

54. Torrent, Torrent Pharmaceuticals, and Torrent Pharma are referred to collectively as the Torrent Defendants in this Complaint.

D. Retail Pharmacy Defendants

55. Retail pharmacies have supply arrangements with finished-dose manufacturers. They stand in direct contractual privity with consumers, insofar as retail pharmacies (be they brick-and-mortar or mail-order) are the entities that dispensed and received payments for the contaminated, adulterated, and/or misbranded VCDs for which consumers paid and consumed.

56. The following Defendants are collectively referred to as the "Pharmacy Defendants."

1. Walgreens

57. Defendant Walgreens Boots Alliance, Inc. ("Walgreens") is a national retail pharmacy chain incorporated in the State of Delaware with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois.

58. Walgreens is one of the retail pharmacy chains in the United States, offering retail pharmacy services and locations in all 50 states including the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. As of August 31, 2018, Walgreens operated 9,560 retail pharmacies across the United States, with 78% of the U.S. population living within five 5 miles of a store location. In addition, Walgreens recently purchased an additional 1,932 store locations from rival Rite Aid Corporation, further consolidating the industry. Walgreens' sales amounted to a staggering $98.4 billion in 2018, most of which are generated for

prescription sales. Walgreens accounts for nearly 20% of the U.S. market for retail prescription drug sales.

59. Walgreens is one of the largest purchasers of pharmaceuticals in the world, and according to its Form 10-K for 2018, the wholesaler AmerisourceBergen "supplies and distributes a significant of generic and branded pharmaceutical products to the [Walgreens] pharmacies."

60. In or about 2017, Walgreens acquired control of Diplomat Pharmacy. "Walgreens," as defined herein, includes any current or former Diplomat pharmacy.

61. Defendant Walgreens sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers during the class period as defined below.

2. CVS

62. Defendant CVS Health Corporation ("CVS Health") is a national retail pharmacy chain incorporated in Delaware with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island.

63. As of March 31, 2019, Defendant CVS Health maintained approximately 9,900 retail pharmacy locations across the United States, making it one of the largest in the country. Defendant CVS Health also operates

approximately 1,100 walk-in medical clinics and a large pharmacy benefits management service with approximately 94 million plan members.

64. According to its 2018 Annual Report, Defendant CVS Health's "Pharmacy Services" segment:

65. provides a full range of pharmacy benefit management ("PBM") solutions, including plan design offerings and administration, formulary management, retail pharmacy network management services, mail order pharmacy, specialty pharmacy and infusion services, Medicare Part D services, clinical services, disease management services and medical spend management. The Pharmacy Services segment's clients are primarily employers, insurance companies, unions, government employee groups, health plans, Medicare Part D prescription drug plans ("PDPs"), Medicaid managed care plans, plans offered on public health insurance exchanges and private health insurance exchanges, other sponsors of health benefit plans and individuals throughout the United States.

66. CVS Health's Pharmacy Services segment generated U.S. sales of approximately $134.1 billion in 2018.

67. CVS Health's Retail/LTC segment is responsible for the sale of prescription drugs and general merchandise. The Retail/LTC segment generated approximately $84 billion in U.S. sales in 2018, with approximately 75% of that attributed to the sale of pharmaceuticals. During 2018 the Retail/LTC segment

filled approximately 1.3 billion prescriptions on a 30-day equivalent basis. In December 2018, CVS's share of U.S. retail prescriptions accounted for 26% of the United States retail pharmacy market.

68. In or about 2015, CVS Health acquired all of Target Corporation's pharmacies. "CVS," as defined herein, includes any current or former Target pharmacy.

69. In 2014, CVS Health and wholesaler Defendant Cardinal Health, Inc. ("Cardinal") established a joint venture to source and supply generic pharmaceutical products through a generic pharmaceutical sourcing entity named Red Oak Sourcing, LLC ("Red Oak"), of which CVS Health and Cardinal each own fifty percent. Most or all of the valsartan-containing drugs purchased by CVS Health were acquired through this joint venture with Cardinal.

70. Defendant CVS Health sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers during the class period as defined below.

3. Walmart

71. Defendant Walmart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

72. According to Defendant Wal-Mart's 2018 Form 10-K, Wal-Mart maintains approximately 4,769 retail locations in all fifty states nationwide and the

District of Columbia and Puerto Rico (including supercenters, discount stores, and neighborhood markets and other small format locations). Most or all of these locations have Wal-Mart health and wellness products and services, which includes prescription pharmaceutical services. There are another approximately 600 Sam's Club locations across the United States, all or nearly all offering prescription pharmaceutical services.

73. Defendant Wal-Mart (including Sam's Club) sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers across the country during the class period as defined below.

4. Rite-Aid

74. Defendant Rite-Aid Corporation ("Rite-Aid") is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania.

75. Defendant Rite-Aid sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers during the class period as defined below.

5. Express Scripts

76. Defendant Express Scripts, Inc. is a corporation with its principal place of business at One Express Way, St. Louis, MO 63121. Defendant Express Scripts, Inc. is a subsidiary of Express Scripts Holding Company

77. Defendant Express Scripts Holding Company is a corporation with its principal place of business at One Express Way, St. Louis, MO 63121.

78. Collectively, Express Scripts, Inc. and Express Scripts Holding Company are referred to as "Express Scripts."

79. Express Scripts sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers during the class period as defined below.

6. Kroger

80. Defendant The Kroger, Co., ("Kroger") is a corporation, with its principal place of business at 1014 Vine Street, Cincinnati, OH 45202.

81. Defendant Kroger sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers during the class period as defined below.

7. Albertsons

82. Defendant Albertsons Companies LLC ("Albertsons") is a limited liability company with its principal place of business in Boise, Idaho.

83. Defendant Albertson sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers during the class period as defined below.

8. OptumRx

84. Defendant OptumRx is a Minnesota corporation with its principal place of business at 2300 Main Street, Irvine, CA 92614.

85. Defendant Optum, Inc. is a Minnesota corporation with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344. Upon information and belief, Defendant Optum Rx is a wholly-owned subsidiary of Defendant Optum, Inc.

86. Defendants OptumRx and Optum, Inc. sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers during the class period as defined below.

9. Humana Pharmacy

87. Defendant Humana Pharmacy, Inc. is a corporation with its principal place of business at 500 West Main Street, Louisville, KY 40202.

88. Defendant Humana Pharmacy, Inc. sold a large portion of the contaminated, adulterated, and/or misbranded VCDs to U.S. consumers during the class period as defined below.

E. Wholesaler Defendants

89. Wholesalers are entities that purchase, among other things, drugs from finished-dose manufacturers and sell or provide those drugs to retail pharmacies and others.[12]

1. Cardinal Health

90. Cardinal is an Ohio corporation with its principal place of business at 7000 Cardinal Place, Dublin, Ohio 43017. Cardinal has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic VCDs in the United States, including in the State of New Jersey.

91. Defendant Harvard Drug Group, L.L.C. ("Harvard") is a Michigan limited liability company with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, Michigan 48152. It is a wholly-owned subsidiary of Cardinal. At all times material to this case, Harvard has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded VCDs in the United States, including in the State of New Jersey.

92. Defendant Major Pharmaceuticals, Inc. ("Major") is a corporation with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia,

[12] It is believed that three wholesalers comprise at least 90% of the wholesale drug market, and, likely were the entities that distributed the contaminated, adulterated, misbranded, and/or unapproved VCDs.

Michigan 48152. Major is a wholly-owned subsidiary of Harvard. At all times material to this case, Major has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded VCDs in the United States, including in the State of New Jersey.

93. Cardinal, Harvard, and Major are collectively referred to as the Cardinal Defendants in this Complaint.

2. McKesson

94. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states. McKesson – either directly or through a subsidiary or affiliated – distributed contaminated, adulterated, and/or misbranded VCDs in the United States, including in the State of New Jersey.

3. AmerisourceBergen

95. Defendant AmerisourceBergen Corporation ("Amerisource") a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states. Amerisource – either directly or through a subsidiary or affiliated – distributed contaminated, adulterated, and/or misbranded VCDs in the United States, including in the State of New Jersey.

F. Repackager and /Relabeler Defendants

96. Drug repackagers and relabelers purchase or obtain drugs from manufacturers or wholesalers, and then repackage and/or relabel the drugs in small quantities for sale to pharmacies, doctors, or others.

97. Defendant A-S Medication Solutions, LLC ("A-S Medication") is a Nebraska corporation with its principal place of business at 224 North Park Avenue, Fremont, NE 68025. A-S Medication is a repackaging company and is listed as the recalling firm for certain batches of VCDs manufactured by Teva and Prinston, with the active pharmaceutical ingredient ("API") from ZHP. A-S Medication sold contaminated, adulterated, and/or misbranded VCDs during the class period.

98. Defendant Bryant Ranch Prepack, Inc. ("Bryant") is a California corporation with its principal place of business at 1919 N. Victory Place Burbank, CA 91504. Bryant is a repackager for the Teva Defendants, and sold API from ZHP. Bryant sold contaminated, adulterated, and/or misbranded VCDs during the class period.

99. Defendant H J Harkins Co., Inc., dba Pharma Pac ("Harkins") is a California corporation, with its principal place of business at 1400 West Grand Avenue, Suite F, Grover Beach, CA, 93433. Harkins is a repackager for VCDs

manufactured by Prinston, which contained API from ZHP. Harkins sold contaminated, adulterated, and/or misbranded VCDs during the class period.

100. Defendant RemedyRepack, Inc. ("Remedy") is a Pennsylvania corporation, with its principal place of business at 625 Kolter Drive, Suite 4, Indiana, PA 15701. Remedy is a repackager for VCDs manufactured by Prinston and by Torrent Pharmaceuticals, with API coming from ZHP. Remedy sold contaminated, adulterated, and/or misbranded VCDs during the class period.

101. Defendant Northwind Pharmaceuticals ("Northwind") is an Indiana corporation with its principal place of business at 9402 Uptown Drive, Suite 1100, Indianapolis, IN, 46256. Northwind is also a repackager for the Teva Defendants. Northwind sold contaminated, adulterated, and/or misbranded VCDs during the class period.

102. Defendant NuCare Pharmaceuticals, Inc. ("NuCare") is a California corporation with its principal place of business at 622 West Katella Avenue, Orange, CA 92867. NuCare sold contaminated, adulterated, and/or misbranded VCDs during the class period.

103. Defendant Preferred Pharmaceuticals, Inc. ("Preferred") is a California corporation with its principal place of business at 1250 North Lakeview Ave., Unit O, Anaheim CA 92807. Preferred is a repackager for VCDs

manufactured by the Hetero Defendants. Preferred sold contaminated, adulterated, and/or misbranded VCDs during the class period.

104. Defendant AvKARE, Inc. ("AvKARE") is a Tennessee corporation with its principal place of business at 615 N 1st Street, Pulaski, TN 38478-2403. AvKARE, serves as a repackager for the Hetero Defendants, as well as the Teva Defendants. Upon information and belief, AvKARE are sold contaminated, adulterated, and/or misbranded VCDs during the class period.

G. True Names / John Doe Defendants 1-50

105. The true names, affiliations, and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of John Does 1 through 50 are unknown to Plaintiffs at this time. Plaintiffs therefore sue these defendants using fictitious names. Each John Doe proximately caused damages to Plaintiffs as alleged below, and each John Doe is liable to Plaintiffs for the acts and omissions alleged below as well as the resulting damages. Plaintiffs will amend this Master Class Complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

106. At all times relevant to this Master Class Complaint, each of the John Does was the agent, servant, employee, affiliate, and/or joint venturer of the other co-defendants and other John Does. Moreover, each Defendant and each John Doe

acted in the full course, scope, and authority of that agency, service, employment, and/or joint venture.

III. JURISDICTION AND VENUE

107. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

108. This Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1407, and because Defendants have sufficient minimum contacts in New Jersey, and because Defendants have otherwise intentionally availed themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

109. Venue is proper in this District on account of the MDL consolidation pursuant to 28 U.S.C. § 1407 and because Defendants reside in this District, 28 U.S.C. § 1391(b)(1); "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Generic Drugs Must Be Chemically the Same as Branded Drug Equivalents

110. According to the FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that **a generic medicine works in the same way and provides the same clinical benefit as its brand-name version.** In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[13]

111. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA, which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand name version in the following ways:

a. The active ingredient(s) in the generic medicine is/are the same as in the brand-name drug/innovator drug.

[13] FDA, GENERIC DRUGS: QUESTIONS & ANSWERS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last visited June135, 2019) (emphasis in original).

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.[14]

112. The drugs ingested by Plaintiffs were approved by the FDA, based upon Defendants' representations that they met the above criteria.

113. ANDA applications do not require drug manufacturers to repeat animal studies or clinical research on ingredients or dosage forms already approved for safety and effectiveness.[15]

114. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same risks and benefits.[16]

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[14] FDA, GENERIC DRUG FACTS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm (last visited June 13, 2019).

[15] FDA, GENERIC DRUGS: QUESTIONS & ANSWERS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last visited June 13, 2019).

[16] *Id.*

B. Misbranded and Adulterated or Misbranded Drugs

115. The manufacture of any adulterated or misbranded drug is prohibited under federal law.[17]

116. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.[18]

117. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[19]

118. Among the ways a drug may be adulterated and/or misbranded are:

a. "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"[20]

b. "if … the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[21]

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[17] 21 U.S.C. § 331(g).
[18] 21 U.S.C. § 331(a).
[19] 21 U.S.C. § 331(c).
[20] 21 U.S.C. § 351(a)(2)(A).
[21] 21 U.S.C. § 351(a)(2)(B).

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. …"[22]

d. "If … any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[23]

119. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[24]

b. "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[25]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[26]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of

[22] 21 U.S.C. § 351(b).
[23] 21 U.S.C. § 351(d).
[24] 21 U.S.C. § 352(a)(1).
[25] 21 U.S.C. § 352(c).
[26] 21 U.S.C. § 352(e)(1)(A)(ii)

administration or application, in such manner and form, as are necessary for the protection of users. …"[27]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[28]

f. "if it is an imitation of another drug;"[29]

g. "if it is offered for sale under the name of another drug."[30]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[31]

i. If the drug is advertised incorrectly in any manner;[32] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[33]

120. As articulated in this Complaint, Defendants' unapproved drug was adulterated and/or misbranded as a result of contamination with NDMA and NDEA, which was not approved, and was not disclosed.

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[27] 21 U.S.C. § 352(f).
[28] 21 U.S.C. § 352(g).
[29] 21 U.S.C. § 352(i)(2).
[30] 21 U.S.C. § 352(i)(3).
[31] 21 U.S.C. § 352(j).
[32] 21 U.S.C. § 352(n).
[33] 21 U.S.C. § 352(p).

C. The Drugs Ingested by Plaintiffs Were Not Valsartan, But New, Unapproved VCDs

121. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[34]

122. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

[34] FDA, HUMAN DRUGS, https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug (last visited June 13, 2019).

123. NDMA and NDEA both cause cellular and genetic injury triggering genetic mutations in humans that can ultimately develop into cancer. These injuries affect the structure of the human body, and thus, NDMA and NDEA are, by definition, active ingredients in a drug.

124. FDA further requires that whenever a new active ingredient is added to a drug, the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.[35]

125. This new and unapproved drug with additional active ingredients (such as nitrosamines in the subject VCDs) cannot be required to have the same label as the brand-name drug, as the two products are no longer the same.

126. At the very least and alternatively, drugs contaminated with different and dangerous ingredients than their brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[36]

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[35] *See* 21 C.F.R. § 310.3(h).

[36] *See generally* Department of Justice, *Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA* (May 13, 2013), https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.

127. Because the VCDs ingested by Plaintiffs were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs. Further, if such as assessment were performed, the drugs would not have been approved with the NDMA and NDEA contamination.

128. The inclusion of additional active ingredients (NDMA and NDEA), and potentially other deviations from Defendants' ANDA approvals rendered Defendants' VCDs unapproved, adulterated, misbranded drugs that are distinct from the FDA-approved generic valsartan.

129. Plaintiffs reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

D. Defendants Made False Statements in the Labeling of its VCDs

130. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[37] and conform to requirements governing the appearance of the label.[38]

[37] 21 C.F.R. § 201.5.
[38] 21 C.F.R. § 801.15.

131. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[39] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

132. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[40]

133. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[41]

134. In addition, by referring to their drugs as "valsartan" or "valsartan HCT" or "amlodipine-valsartan" or "amlodipine-valsartan HCT" Defendants were making false statements regarding their VCDs.

135. Because NDMA and/or NDEA were not disclosed by Defendants as ingredients in the VCDs ingested by Plaintiffs, the Defendants failed to warn consumers and physicians of the true ingredients, and the subject drugs were misbranded.

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[39] *Id.*; 65 Fed. Reg. 14286 (March 16, 2000).
[40] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).
[41] 21 C.F.R. § 201.6; 201.10.

136. It is unlawful to introduce a misbranded drug into interstate commerce.[42] Thus, the VCDs ingested by individual Plaintiffs were unlawfully distributed and sold.

E. The Generic Drug Supply Chain in the United States

137. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

138. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, the active pharmaceutical ingredient manufacturer ("API")). Generic drug manufacturers may sell to other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

139. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and Amerisource Bergen Corporation.

140. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

[42] 21 U.S.C. § 331(a).

F. Background on Current Good Manufacturing Practices ("cGMPs")

141. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

142. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

143. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these

regulations if the facility is making drugs intended to be distributed in the United States.

144. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

145. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

146. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

147. There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality

control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

148. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

149. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

150. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

G. The Generic Drug Approval Framework

151. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

152. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

153. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

154. By contrast, generic drug companies submit an ANDA. Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

1. ANDA Applications Must Demonstrate Bioequivalence

155. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two

drug products is evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

156. As part of its showing of bioequivalence pursuant to 21 C.F.R. § 314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

> a full description of the drug's substance, including its physical and chemical characteristics and stability; and
>
> the specifications necessary to ensure the identify strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

157. Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement

of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

158. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

2. ANDA Applications Must Provide Information About the Manufacturing Plants and Processes

159. The ANDA application must also include information about the manufacturing facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

160. The ANDA application must include a description of the manufacturing process and facility and the manufacturing process flow chart showing that there are adequate controls to ensure the reliability of the process.

161. Furthermore, the ANDA application must contain information pertaining to the manufacturing facility's validation process, which ensures that the manufacturing process produces a dosage that meets product specifications.

3. ANDA Applications Must Comply with cGMPs

162. Additionally, ANDA applications must include certain representations pertaining to compliance with cGMPs.

163. The ANDA application is required to contain cGMP certifications for both the ANDA applicant itself, and also and the drug product manufacturer (if they are different entities).

4. ANDA Approval is Contingent upon Continuing Compliance with ANDA Representations of Sameness

164. Upon granting final approval for a generic drug, the FDA will typically state that the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD[43] branded drug. Pharmacists, physicians, and patients can expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each prescription of its generic products. Further, by simply marketing generic drugs pursuant to the brand-name drug's label under the generic name (e.g., valsartan or valsartan HCT), generic manufacturers warrant that the generic drug is therapeutically equivalent to the brand-name drug.

[43] The FDA's Drug Glossary defines an RLD as follows: "A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart."

165. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

166. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, the generic manufacturer may no longer rely on the brand-name drug's labeling.

167. According to the FDA, there are at least sixteen ANDAs approved for generic DIOVAN, nine for generic DIOVAN HCT, nine for generic EXFORGE, and five for generic EXFORGE HCT.

H. Approval of ANDAs Related to Valsartan

1. DIOVAN and EXFORGE Background

168. Valsartan is a potent, orally active nonpeptide tetrazole derivative which causes a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and post-myocardial infarction. Millions of American consumers use VCDs for the treatment of these medical conditions.

169. Valsartan and its combination therapy are the generic versions of the DIOVAN and DIOVAN HCT, which were marketed in tablet form by Novartis AG ("Novartis") beginning in July 2001 (in tablet form) and March 1998,

respectively, upon approval by the FDA. Valsartan's combination therapy with amlodipine, as well as the combination therapy of valsartan, amlodipine and hydrochlorothiazide, are the generic versions of Novartis's branded products EXFORGE and EXFORGE HCT. Novartis received the FDA's approval for EXFORGE in June 2007 and for EXFORGE HCT in April 2009.

170. These Valsartan based branded drugs proved to be blockbuster products for Novartis. Globally, DIOVAN and DIOVAN HCT generated $5.6 billion in sales in 2011 according to Novartis's Form 20-F for that year, of which $2.33 billion was from the United States. The same year, EXFORGE and EXFORGE HCT had $325,000,000 in U.S. sales and $884,000,000 globally.

171. DIOVAN's, DIOVAN HCT's, EXFORGE's, and EXFORGE HCT's FDA-approved labels specify the active and inactive ingredients. None of the contaminants at issue here (including NDMA, NDEA, or other nitrosamines) are FDA-approved ingredients of DIOVAN, DIOVAN HCT, EXFORGE, or EXFORGE HCT. Nor are any of these contaminants FDA-approved ingredients of any generic valsartan-containing product approved pursuant to an ANDA.

172. Novartis's DIOVAN and EXFORGE patents expired in September 2012. Defendant Mylan launched a DIOVAN HCT generic in or about September 2012 when its valsartan HCT ANDA was approved by the FDA. Generic versions of the other drugs followed in the intervening years.

2. ANDA Applications for Generic Valsartan

173. Almost a full decade before the DIOVAN patents were set to expire, generic drug manufacturers started filing ANDA applications for their own generic versions of the Valsartan drug.

174. Hatch-Waxman rewards the first generic company to file a substantially complete ANDA containing a Paragraph IV certification with a 180-day period of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is triggered upon either a first commercial marketing of the drug (including of the RLD) by the 180-day exclusivity holder or the date on which a court has entered a judgment finding that the patent subject to the Paragraph IV certification is invalid, unenforceable, or not infringed.

175. On December 24, 2004, Ranbaxy Labs ("Ranbaxy") filed the first ANDA application for Valsartan (the generic equivalent of the DIOVAN product).

176. On January 7, 2005, Teva filed the second ANDA application for Valsartan (the generic equivalent of the DIOVAN product), for which it received tentative approval on January 7, 2005.

177. On September 15, 2008, Mylan filed an ANDA application for Valsartan (the generic equivalent of the DIOVAN product).

178. Upon information and belief, in the intervening years after these three initial ANDA applications, all other Defendants filed ANDA applications for either

Valsartan (the generic equivalent of the DIOVAN product), Valsartan hydrochlorothiazide (the generic equivalent of the DIOVAN HCT product), Valsartan Amlodipine (the generic equivalent of the EXFORGE product), and Valsartan Amlodipine Hydrochlorothiazide (the generic equivalent of the EXFORGE HCT product).

179. Despite the number of ANDAs that had been filed as early as 2004, when DIOVAN's patent expired in 2012, no generic entered the market.

180. As the first to have filed their ANDA application in December of 2004, Ranbaxy was entitled to exclusivity, and as such, no other ANDAs would be approved until Ranbaxy received final approval.

181. Defendants Mylan and Teva were among those who had tentative approval and were ready to launch their generic DIOVAN Product upon expiration of the DIOVAN patent in 2012.

182. Indeed, Defendant Mylan launched its generic DIOVAN HCT product, for which it had filed an ANDA and received approval, on September 21, 2012, the same day the DIOVAN patent was set to expire.

183. After delaying its approval due to gross manufacturing defects plaguing Ranbaxy's Indian API manufacturing facilities, the FDA finally approved Ranbaxy's generic Valsartan in June of 2014.

184. Six months later, after Ranbaxy's period of exclusivity expired, Mylan's generic DIOVAN product launched on January 5, 2015, and Teva's generic VCDs launched January 6, 2015. The entry of the rest of the generic equivalents of these drugs followed thereafter.

185. Par Pharmaceuticals received approval of the first generic EXFORGE in September 2014, and Teva received approval of the first generic EXFORGE HCT in December 2014. The entry of the rest of the generic equivalents of these drugs followed thereafter.

I. Starting as Early as 2007, Defendants Were Actively Violating cGMPs in Their Foreign Manufacturing Facilities

186. For some time, Defendants have known that generic drugs manufactured overseas, particularly in China and India, were found or suspected to be less safe and effective than their branded equivalents or domestically-made generics due to their grossly inadequate manufacturing processes, procedures and compliance with cGMPs.

187. Defendants' foreign manufacturing operations were no exception to this.

1. ZHP's Inadequate Manufacturing Processes Results in Adulterated, Misbranded VCDs

188. ZHP has Active Pharmaceutical Ingredient ("API") manufacturing facilities located in Linhai City, Zhejiang Province, China. According to ZHP's

website, ZHP was one of the first Chinese companies approved to sell generic drugs in the United States, and it remains one of China's largest exporters of pharmaceuticals to the United States and the European Union.

189. ZHP serves as a contract API manufacturer of numerous defendants' VCDs as set forth *supra* at Section II, and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

190. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

191. On or about March 27-30, 2007, the FDA inspected ZHP's Xunqiao Linhai City facilities. That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public.

192. The FDA inspected ZHP's same Xunqiao facility again on November 14-18, 2016. The inspection revealed four violations of cGMPs. First, "[w]ritten procedures designed to prevent contamination of drug products purporting to be sterile are not followed." Second, ZHP had failed "to establish laboratory controls that include scientifically sound and appropriate specifications, standards,

sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." Third, "[p]rocessing areas are deficient regarding the system for cleaning and disinfecting the equipment." Last, "data is not recorded contemporaneously."

193. On May 15-19, 2017, the FDA inspected ZHP's facility at Coastal Industrial Zone, Chuannan No. 1 Branch, Linhai City, Zhejiang Province, China. ZHP manufactures all of its valsartan API at this Chuannan facility. That inspection resulted in the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter and investigation up to that point. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated." These findings were not made fully available to the public. However, this information was shared or available to ZHP's finished-dose manufacturers, as well as those Defendants further down the distribution chain.

194. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution from the environment" surrounding the facility. These manipulations of sampling were components of a pattern and

practice of systematic data manipulation designed to fail to detect and/or intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA and NDEA.

195. The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and there were black metallic particles in API batches.

196. The FDA inspector "noted reoccurring complaints pertained to particulate matter in API … and for discrepancies in testing between [ZHP] and their consignees.… To address the firm's handling of complaints describing testing disparities, [the inspector] had the firm generate a list of such complaints, as well as associated pie charts.… From 2015 until May 2017, 13 complaints related to discrepancies between [ZHP]'s test results and their consignees were listed. Of these complaints 85% had what the firm termed 'Customer has no subsequent feedback or treatment.' Specifically, this 85% was further broken down into 3 categories: the batch subject to the complaint was sent to other consignees who did not report a complaint, there is a test method discrepancy and feedback was

provided to the consignee without a response, and the consignee failed to respond but continued to purchase API from [ZHP]."

197. On November 29, 2018, the FDA issued Warning Letter 320-19-04 to ZHP based on its July 23 to August 3, 2018 inspection of its Chuannan facility.[44] The letter summarized "significant deviations from [cGMPs] for [APIs]." The FDA consequently informed ZHP that its "API are adulterated and/or misbranded within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."

198. The FDA explained that ZHP repeatedly failed "to ensure that quality-related complaints are investigated and resolved," including complaints related to peaks of NDMA in its products as early as 2012.

199. ZHP also failed "to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." More specifically, ZHP "approved a [V]alsartan API process change … that included the use of the solvent [redacted]. [ZHP's] intention was to improve the manufacturing process, increase product yield, and lower production costs. However, [ZHP] failed to adequately assess the potential formation of mutagenic impurities[, such as NDMA,] when [it] implemented the new process. Specifically, [it] did not consider

[44] FDA, *Zhejiang Huahai Pharmaceutical 11/29/18*, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm628009.htm.

the potential for mutagenic or other toxic impurities to form from [redacted] degradants, including the primary [redacted] degradant, [redacted]. According to [ZHP's] ongoing investigation, [redacted] is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process."

200. The FDA added that ZHP "also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in [its] [V]alsartan API before [it] approved the process change. [ZHP is] responsible for developing and using suitable methods to detect impurities when developing, and making changes to, [its] manufacturing processes."

201. ZHP claimed that it had followed "common industry practice." Importantly, the FDA reminded ZHP that "common industry practice may not always be consistent with CGMP requirements and that [it is] responsible for the quality of drugs [it] produce[s]." The FDA "strongly" recommended that ZHP hire a cGMP consultant and referred ZHP to four guides on cGMPs.

202. On September 28, 2018, the FDA stopped allowing ZHP to deliver drugs made at its Chuannan facility into the United States. The Warning Letter stated that "[f]ailure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at [ZHP's Chuannan facility] into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3).

Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B)."

203. After the recalls of ZHP's VCDs, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at its Linhai City facilities contained NDMA levels hundreds of times in excess of the FDA's interim limits[45] of 96 ng/day or 0.3 ppm.[46] Specifically, VCDs manufactured at ZHP for ZHP's subsidiary Prinston Pharmaceutical contained NDMA levels of between 15,180 and 16,300 ng, while Valsartan HCT manufactured at ZHP contained NDMA levels of between 13,180 and 20,190 ng.[47] ZHP valsartan API manufactured for Teva and Torrent Pharmaceuticals contained similarly high levels of NDMA.

204. In addition, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at ZHP's Linhai City facilities for Torrent

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[45] To be clear, ZHP's valsartan products should not contain any NDMA.

[46] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products (last visited June 13, 2019); *see also* FDA, FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last visited June 13, 2019).

[47] *Id.*

Pharmaceuticals contained NDEA levels upwards of fifty times in excess of the FDA's interim limits[48] of 26.5 ng/day or 0.083 ppm. Specifically, FDA testing reveals up to 1,310 ng of NDEA in Torrent Pharmaceuticals' VCDs. ZHP valsartan API manufactured for Teva contained similarly high levels of NDEA (up to 770 ng).

2. Hetero's Inadequate Manufacturing Processes Results in Adulterated, Misbranded VCDs

205. Defendant Hetero maintains six API manufacturing facilities in India, which have been approved by the FDA to produce active ingredients for drugs being sold and marketed in the United States.

206. Hetero has a history of deviations from FDA's cGMP standards.

207. In December of 2016, during an inspection of an oral solid dose drug product manufacturing facility, the FDA observed, through closed circuit TV surveillance, that Hetero Quality Assurance technicians and "other individuals" were recorded destroying and altering records pertaining to commercial batch manufacturing immediately before the FDA's onsite regulatory inspection. According to a scathing letter, the FDA noted that the following occurred:

a. Hetero employees brought in a document shredder into the "DOCUMENTS STORAGE AREA" four days prior to the FDA inspection;

[48] To be clear, Torrent Pharmaceuticals' and Teva's valsartan products should not contain any NDEA.

b. The FDA observed extensive shredding of what appeared to be "controlled documents" as well as "extensive signing of documents" by Quality Assurance technicians. The FDA noted that the documents were of a color consistent with batch packaging records and batch manufacturing record. Hetero failed to maintain documentation of what had been shredded;

c. One day prior to the FDA inspection a Hetero contract employee in the Quality Assurance division removed documents from the shredder and placed them in his pocket; and

d. At 1:13 am the morning the FDA inspectors were set to arrive at Hetero for their regulatory inspections, individuals were seen shredding documents.

208. In addition to the documented destruction of these manufacturing records, the FDA further observed that production and control records were not prepared for each batch of drug product produced and did not include complete information relating to the production and control of each batch.

209. Additionally, data derived from Hetero's programmable logic controller for compression machines was inconsistent with batch records and validation reports that were submitted to the FDA in support of applications to manufacture and market drugs in the United States.

210. Hetero also failed to include findings of any investigations and follow-up that occurred as a result of investigations into complaints about their drugs.

211. During the December 2016 inspection, equipment at Hetero was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of Hetero drug products.

212. During the December 2016 visit, FDA inspectors found that "accuracy, sensitivity and reproducibility of test methods" were not established and documented.

213. In an August 15, 2017, warning letter, the FDA strongly recommended that Hetero engage "a consultant, qualified as set forth in 21 CFR 211.34" to assist Hetero Labs in meeting cGMP requirements, but that, ultimately, "executive management remains responsible for fully resolving all deficiencies and ensuring ongoing cGMP compliance."

214. In February of 2018, FDA investigators discovered other manufacturing flaws at an API Manufacturing facility.

215. For example, the FDA found that there was a "failure" by Hetero to "thoroughly review any unexplained discrepancy and failure of a batch or any of

its components to meet any of its specifications," whether or not the batch had been already distributed.

216. The FDA investigators further found during that February 2018 inspection that Hetero employees who were engaged in the processing, holding and testing of a drug product lacked the training and experience required to perform their assigned functions. Indeed, in a walk-through with FDA investigators, several quality-control personnel could not explain their assigned functions and processes after "repeated opportunities" to do so.

217. Additionally, FDA investigators concluded that there was "no assurance" that equipment used in API production was being maintained and/or kept under proper conditions for manufacturing operations "to prevent the contamination of the products handled and/or processed in the equipment." Likewise, equipment at the Hetero was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of Hetero's drug products.

218. After the recalls of Hetero's VCDs, FDA Laboratory Analysis testing would later reveal that valsartan 320mg API manufactured by Hetero contained NDMA levels in excess of the FDA's interim limits[49] of 96 ng/day or 0.3 ppm.[50]

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[49] To be clear, Hetero's valsartan products should not contain any NDMA.

[50] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-

3. Mylan's Inadequate Manufacturing Processes Results in Adulterated, Misbranded VCDs

219. While ZHP and Aurobindo began as foreign companies who eventually expanded their operations to the United States, Mylan's history begins in the United States back in 1961, in White Sulfur Springs, West Virginia.

220. From the founding of the company, to roughly the mid-2000s, Mylan either manufactured their own products domestically in the United States, or contracted with foreign companies to order API for their finished dosage products.

221. However, in late 2005, Mylan's CEO at the time, Robert Coury, was facing a crisis due to the fact that the US-based company was losing market share to Indian drug companies that made their own API in-house and operated at rock-bottom costs. At the time, Mylan had to order API from Chinese and Indian suppliers.

222. Consequently, in December of 2005, Coury hammered out a deal to acquire Matrix Laboratories, an India-based company which had been of Mylan's ingredient suppliers. At the time of the acquisition of Matrix Laboratories, a former Ranbaxy employee named Rajiv Malik was the CEO of Matrix.

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valsartan-products (last visited June 13, 2019); *see also* FDA, FDA UPDATES AND PRESS ANNOUNCEMENTS ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS (VALSARTAN, LOSARTAN, AND IRBESARTAN), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last visited June 13, 2019).

223. After the Mylan acquisition in 2006, Malik became the executive vice president in charge of global technical operations.

224. Malik's impact on Mylan was immediate – he reoriented the company towards India. Very quickly, the number of drug applications for generics Mylan submitted to the FDA tripled, and the approvals doubled.

225. Indeed, Malik's compensation structure was based, in part, on the number of ANDA applications filed with global regulators.

226. As the focus shifted to bringing more and more drugs to market, employees in both India and the United States began to experience a shift in the company, where speed was prized above all else. Employees who insisted on adhering to cGMPs felt sidelined and were tagged as slow.

227. In 2013, Malik was tasked with overseeing Mylan's biggest foreign acquisition yet – a $1.6 billion purchase of Agila Specialties, a manufacturing facility in India.

228. In comments regarding the potential acquisition, Mylan CEO Heather Bresch (daughter of US Senator Joe Manchin) touted the "state-of-the-art, high quality" manufacturing platforms in the industry.

229. However, months after Mylan announced the acquisition, the FDA conducted an investigation of the facility in June of 2013. In a scathing investigation report, it found that key pieces of equipment were stored in non-

sterile areas, and then never resanitized before use; employees failed to wash their hands in the bathroom; technicians were wearing gloves that were flaking and had pinholes; and supposedly sterile gloves were found to be stored in boxes with crushed insects.

230. Making matters worse, after the June inspection, in a letter written by the FDA in September, the FDA found that Agila's written response "minimizes the importance of ensuring glove integrity and its potential impact on product quality." It also found that the issues led the FDA to "question [Agila's] understanding of basic microbiology and microbial controls that are critical for the manufacture of sterile products."

231. However, despite these gross manufacturing issues, Mylan moved forward on its billion-dollar acquisition, eventually obtaining the company and their manufacturing facilities.

232. Throughout 2014 and 2015, the FDA continued to investigate Mylan's Indian manufacturing facilities, routinely uncovering a multitude of violations of the cGMPs, and finding that Mylan responded with letters that lacked corrective action. These violations included failure to establish and follow written procedures to prevent microbiological contamination of drug products, lack of assurance that the manufacturing facilities were sterile, and failures to thoroughly investigate

unexplained discrepancies in batches or whether the components met specifications.

233. In 2015, a former Mylan employee sat down with FDA employees and alleged that the research and development centers in Hyderabad had become a hub for data fraud.[51]

234. The Mylan whistleblower identified specific applications for drugs that were due to be launched into the American market, claiming that in order to generate passing results for some drug products, Mylan had manipulated the testing, by switching the tests from batch testing to pilot batches (which were easier to control, but not as reliable in ensuring the results as they were smaller in size).[52]

235. The Mylan whistleblower also claimed that the Mylan team had evolved its fraudulent methods to evade detection. For example, instead of deleting manipulated data from the plant's software systems, which would have left a trail of metadata that could be uncovered by the FDA, plant managers were deliberately corrupting the data they wanted to hide.[53]

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[51] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 328.
[52] *Id.*
[53] *Id.*

236. In July of 2016, upset by the failure of the FDA to investigate, the Mylan whistleblower sent an email to FDA officials that said: "I learned that Mylan's strategy of providing employment to FDA members has been working very well…Perhaps the agency awaits a definitive tragedy to occur on U.S. soil due to sub-standard generic products not meeting the safety & efficacy standards."[54]

237. The email had the intended effect. Two months later, in September 2016, the FDA inspected the Mylan India facilities.[55]

238. Over the course of the week-long inspection, the FDA found evidence that the plant's software system was riddled with error messages showing "instrument malfunction," or "power loss," as though Mylan was literally pulling the plug from the wall to stop the creation of metadata showing failed testing.

239. In confidential correspondence with the FDA, Mylan tried to explain the high number of data error messages (42 over a seven-day period), saying there was accidental knocking of cables off of tables, or through electronic loss of signals. For another error that was observed (150 times over seven days), the

[54] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 329.
[55] *Id.*

partial explanation given by Mylan was that some software settings led to the "unintended consequence of a number of repetitive error messages."[56]

240. The FDA didn't accept these excuses. In a stern warning letter sent to Malik in April of 2017, the FDA effectively froze the site's applications until the company took corrective actions. The letter noted that Mylan's quality systems did not "adequately ensure the accuracy and integrity of the data."[57]

241. But Mylan's issues were not solely limited to its India operations. Several months after the April 2017 letter regarding the India operations, Mylan operations in West Virginia were under scrutiny. The allegations were that laboratory technicians had failed to investigate anomalous results and had instead falsified records to cover-up any anomalous results. Regulators were "stunned" by the lapses, finding the practices "egregious," and questioned whether Mylan was being "transparent at all of its sites."[58]

242. The inspectors also found bins full of shredded documents, including quality-control records, in Parts of the factory where every piece of paper is supposed to be saved. [59]

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[56] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 331.
[57] *Id.*
[58] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 332.
[59] https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost

243. The list of alleged infractions became so long that a fourth inspector was added. A warning letter, the FDA's strongest rebuke, was drafted. [60]

244. Ultimately, the FDA's director of the Office of Manufacturing Quality, Tom Cosgrove, made the controversial decision, over the strenuous objections of staff in two separate FDA divisions, to downgrade the investigators' negative findings at Morgantown, from Official Action Indicated to Voluntary Action Indicated.[61]

245. In an email to FDA colleagues, Cosgrove acknowledged their view that the company's practices were "more widespread and that Mylan's investigation was insufficient," but ultimately defended his decision and said that he had no reason to believe that Mylan would not "remediate voluntarily."

246. However, while Mylan's Morgantown plant was no longer receiving intensive agency scrutiny, it did little to resolve the issues.

247. In early 2018, a whistleblower from inside the Morgantown plant reached out to the FDA to report deteriorating conditions, from understaffing to cleaning lapses. The whistleblower from inside the plant claimed that Mylan management was focused on creating a "façade of documents" to fend off the

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[60] Anna Edney, *America's Love Affair With Cheap Drugs Has a Hidden Cost*, BLOOMBERG (Jan. 29, 2019), https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost.

[61] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 333.

FDA, according to an agency memo that detailed the allegations. The whistleblower also notified the FDA that Mylan had brought in a team of employees from India to the Morgantown, WV facility, to rapidly close a backlog of company investigations, and that employees were instructed not to question their work.[62]

248. Consequently, the FDA inspected the Morgantown, WV facility again in March and April of 2018. The inspectors found a host of new violations, including that Mylan's manufacturing equipment was not cleaned at appropriate intervals to prevent contamination, and that Mylan's attempts to address the purported testing from the 2016 inspection was "not adequate." [63]

249. On November 20, 2018, Mylan initiated a recall on the consumer level of select lots of VCDs, due to adulteration of the products with NDEA.

4. Aurobindo's Inadequate Manufacturing Processes Results in Adulterated, Misbranded VCDs

250. Aurobindo has API manufacturing facilities located in Hyderabad, Telangana, India.

251. Aurobindo manufactures VCD for each Aurobindo Defendant at these facilities, and Aurobindo Defendants thus have quality assurance obligations with

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[62] *Id.*

[63] Anna Edney, *America's Love Affair With Cheap Drugs Has a Hidden Cost*, BLOOMBERG (Jan. 29, 2019), https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost.

respect to Aurobindo's processes and finished products as set forth above pursuant to federal law.

252. Aurobindo has a history of deviations from FDA's cGMP standards.

253. After an inspection of a Hyderabad facility from June 27 to July 1, 2016, the FDA told Aurobindo that its "[i]nvestigations are inadequate." The FDA explained that Aurobindo failed to initiate stability testing, and "[t]he deviation record contains field 'Number of previous deviations in this product/system.' This field requires previous deviations of the same product or deviation type to be reported, no previous deviations were reported in this field." Moreover, "[t]his is a repeat observation from the 2014 inspection."

254. Three months later, the FDA returned to Aurobindo's Hyderabad facilities and found four noteworthy manufacturing problems. First, "[a]n [redacted] Field Alert was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product." Second, "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform [sic] to appropriate standards of identity, strength, quality and purity." Third, "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Fourth, the

"use of instruments and recording devices not meeting established specifications was observed."

255. In October 2016, the FDA observed that Aurobindo's nearby Borpatla facility had inadequately validated equipment cleaning procedures.

256. In April 2017, the FDA observed that the manufacturing equipment in Aurobindo's Hyderabad facilities "is not always maintained to achieve its intended purposes." "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity." "Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit." "[C]orrective and preventative actions (CAPAs), identified and initiated because of out of specifications (OOS) laboratory investigations, do not correlate to the identified root cause. In certain cases, CAPAs are not initiated at all." "Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." "Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel." "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established."

257. Four months later, the FDA reiterated that "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Second, "[c]ontrol procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."

258. In February 2018, the FDA made nine more disturbing observations at Aurobindo's Hyderabad facilities. First, "Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions." Second, "[e]quipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product." Third, "[e]quipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." Fourth, "[b]uildings used in manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds[,] insects, and other vermin." Fifth, "[p]rocedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and

reassembling equipment as necessary to assure proper cleaning and maintenance." Sixth, "[e]mployees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions." Seventh, the "statistical quality control criteria fail to include appropriate acceptance levels and rejection levels." Eighth, "[e]stablished laboratory control mechanisms are not followed and documented at the time of performance." Lastly, "[a]ppropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel."

259. After the recalls of Aurobindo's VCDs, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by Aurobindo contained NDEA exceedances well in excess of the FDA's interim limits[64] of 26.5 ng/day or 0.083 ppm.[65]

260. Aurobindo has made no efforts or grossly inadequate efforts to correct the previously identified errors, and continues to engage in grossly inadequate

[64] To be clear, Aurobindo's valsartan products should not contain any NDEA.

[65] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products (last visited June 13, 2019); *see also* FDA, FDA UPDATES AND PRESS ANNOUNCEMENTS ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS (VALSARTAN, LOSARTAN, AND IRBESARTAN), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last visited June 13, 2019).

manufacturing processes. During an inspection *one month ago this year* (May 2019), an investigator made note of a panoply of serious issues which called the integrity of the API manufacturing operations into question.

261. For example, in determining that the Medchal, Telangana facility was not following quality control measures, and likewise did not have quality control procedures in place, the investigator observed "loose handwritten notebooks with what appears to be laboratory test data results."

262. Additionally, while Aurobindo claimed to have performed tests and quality control activities on API as a result of the FDA's investigation into adulterated VCDs, during the inspection, the investigator found that the API was not being adequately retained and/or appropriately identified, calling Aurobindo's testing of this API into question. More troubling, this API sampled and analyzed by the investigator was to set to be shipped into the United States.

263. The investigator also found a slew of data integrity issues. The investigator observed "multiple sequences where interrupted sample injections were injected and showed that the sample did not run, shown on the chromatogram as "incomplete data." The testing systems also allowed certain employees to "verify incomplete data in raw data file." The investigator found that the quality control reviewers attested to practices which "contradict actual review practices

performed by reviews." Were these baseline data issues not enough, the investigator also noted that the facility did not retain adequate backup of the data.

264. The investigator also noted that in addition to all of the gross processing and data integrity issues, *even the building itself* did not have the "suitable construction to facility cleaning, maintenance and proper operations." The investigator noted that in a stability sample storage room, they observed a "PVC pipe connected to an air conditioner unit on one end, and paced in a blue plastic bucket on the other end with approximate 50% of the bucket filled with condensate water." There were four other similar setups in other critical rooms in the facility.

265. After the recalls of Aurobindo's VCDs, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by Aurobindo contained NDEA exceedances well in excess of the FDA's interim limits[66] of 26.5 ng/day or 0.083 ppm.[67]

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[66] To be clear, Aurobindo's valsartan products should not contain any NDEA.

[67] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products (last visited June 13, 2019); *see also* FDA, FDA UPDATES AND PRESS ANNOUNCEMENTS ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS (VALSARTAN, LOSARTAN, AND IRBESARTAN), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last visited June 13, 2019).

J. The Contamination of the VCDs

1. The Nitrosamine Contaminant NDMA

266. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow liquid.[68]

267. According to the U.S. Environmental Protection Agency ("EPA"), "NDMA is a semi-volatile chemical that forms in both industrial and natural processes."[69]

268. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

269. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[70]

270. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[71] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by

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[68] U.S. Public Health Service, *Toxicological Profile For N-Nitrosodimethylamine* (Dec 1989), https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

[69] EPA, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17508.pdf.

[70] *Id.*

[71] *Id.*

several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[72]

271. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[73]

272. Exposure to high levels of NDMA has been linked to liver damage in humans.[74]

273. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[75]

274. Other studies showed an increase in other types of cancers, including but not limited to stomach, colorectal, intestinal, kidney, liver, and other digestive tract cancers.

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[72] *Id.*

[73] *Id.*

[74] *Id.*

[75] U.S. Public Health Service, *Toxicological Profile For N-Nitrosodimethylamine* (Dec 1989) , https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

275. On July 27, 2018, the FDA put out a press release, explaining the reason for its concern regarding the presence of NDMA found in VCDs. In that statement, the FDA provided, in relevant part:

> NDMA has been found to increase the occurrence of cancer in animal studies…Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion.
>
> …
>
> The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.[76]

276. The Environmental Protection Agency classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[77]

277. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

278. Anecdotally, NDMA has also been used in intentional poisonings.[78]

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[76] FDA, FDA UPDATES AND PRESS ANNOUNCEMENTS ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS (VALSARTAN, LOSARTAN, AND IRBESARTAN), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last visited June 13, 2019).

[77] EPA, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17508.pdf.

[78] *See Chase Purdy, A common blood-pressure medicine is being recalled because of a toxic ingredient*, QUARTZ (July 18, 2018), https://qz.com/1330936/the-fda-is-

2. The Nitrosamine Contaminant NDEA

279. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is soluble in water.[79]

280. Like NDMA, NDEA is also classified by DHHS and EPA as a probable human carcinogen and a known animal carcinogen.[80]

281. According to the U.S. Environmental Protection Agency, even short-term exposure to NDEA can damage the liver in humans. Animal studies also demonstrate that chronic ingestion of NDEA can cause liver tumors and other types of tumors as well, including in the kidneys.

282. Hematological effects were also reported in animal studies.[81]

283. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high-to-extreme toxicity from oral exposure.[82]

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recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/.

[79] EPA, *Integrated Risk Information System: N-Nitrosodimethylamine*, https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.

[80] Canada Department of Health, *Information Update - Mylan-Valsartan medications voluntarily recalled as a precaution due to an impurity* (Nov. 29, 2018) , https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/68448a-eng.php; see *also* FDA, *FDA provides update on its ongoing investigation into valsartan products; and reports on the finding of an additional impurity identified in one firm's already recalled products* (Sept. 13, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620499.htm.

[81] EPA, *Integrated Risk Information System: N-Nitrosodimethylamine*, https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.

[82] *Id.*

284. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[83]

285. The New Jersey Department of Health also states that "[t]here may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level."[84]

286. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been shown to cause liver and gastrointestinal tract cancer, among others.[85]

287. The IARC of WHO classifies NDEA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

3. Formation of NDMA and/or NDEA in Defendants' Misbranded, Contaminated VCDs

288. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups, which are gene-mutating groups.[86]

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[83] New Jersey Department of Health, *Right to Know Hazardous Substance Fact Sheet: N-Nitrosodiethylamine* (July 2008), https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).

[84] *Id.*

[85] *Id.*

[86] Ketan Agravat, *Nitroso Impurities In Valsartan: How Did We Miss Them?*, PHARMACEUTICAL ONLINE (Oct. 30, 2018), https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.

289. The reason Defendants' manufacturing process produced these compounds is linked to the tetrazole group that most ARB drugs have, including VCDs. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA and NDEA, as a byproduct of the chemical reactions.[87]

290. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[88]

291. The contaminated VCDs consumed by Plaintiffs and manufactured, labeled, marketed, distributed, and/or sold by Defendants was not therapeutically equivalent to their RLDs, and was not manufactured in compliance with cGMPs.

292. Defendants illegally sold contaminated, adulterated VCDs to Plaintiffs.

293. As a result of the consumption of NDMA and NDEA, Plaintiffs have been harmed, including, but not limited to, suffering cellular and genetic injury which creates and/or increases the risk that Plaintiffs will develop cancer.

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[87] *Id.*

[88] Lutz Muller et al., *A rationale for determining, testing, and controlling specific impurities in pharmaceuticals that possess potential for genotoxicity*, REGULATORY TOXICOLOGY & PHARMACOLOGY 44 (2006) 198–211, http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

294. Medical monitoring of Plaintiffs' conditions is necessary and required because of the nature of cancer, including the need for diagnosis and treatment as early as possible.

295. In the absence of medical monitoring to diagnose and treat cancer as early as possible, Plaintiffs and other Class Members are at an increased risk of suffering from the development and progression of cancer, with delayed diagnosis significantly increasing the risk of harm and death.

K. Defendants Had Actual and/or Constructive Notice of NDMA and/or NDEA Contamination of their Misbranded, Adulterated VCDs

296. The FDA has concluded that "NDMA and NDEA are probable human carcinogens and should not be present in drug products." As alleged above, the VCDs manufactured by the API and Finished Dose Manufacturer defendants were found to contain dangerously high levels of nitrosamines, including NDMA and NDEA, sometimes reaching levels hundreds of times higher than the FDA's interim safety limits.

297. NDMA and NDEA are not FDA-approved ingredients for DIOVAN, EXFORGE, or their generic equivalents. Moreover, none of Defendants' VCDs identify NDMA, NDEA, or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogen active ingredients and are not approved to be included in valsartan API.

Their inclusion in Defendants' VCDs renders the VCDs misbranded and adulterated compared to Defendants' warranties and representations.

298. If Defendants had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint and the FDA's investigation reports and warning letter, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of these nitrosamine contaminants almost immediately.

299. ZHP changed its valsartan manufacturing processes in or about 2012, if not earlier. It is not yet known when the processes changed at Defendants' other API manufacturing facilities.

300. According to the European Medicines Agency ("EMA") – which has similar jurisdiction to that of the FDA – "NDMA was an unexpected impurity believed to have formed as a side product after [ZHP] introduced changes to its manufacturing process in 2012."[89]

301. Most assuredly, NDMA and NDEA are not FDA-approved ingredients for DIOVAN, EXFORGE, or their generic equivalents. None of

[89] *See* European Medicines Agency, *Update on Review of Recalled Valsartan Medicines* (August 2, 2018), http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/08/news_detail_003000.jsp&mid=WC0b01ac058004d5c1.

Defendants' VCDs identifies NDMA, NDEA, or any other nitrosamine as an ingredient on the products' labels or elsewhere. Their inclusion in Defendants' VCDs renders the VCDs misbranded and adulterated compared to Defendants' warranties and representations. Their inclusion in Defendants' VCDs renders the VCDs misbranded and adulterated compared to Defendants' warranties and representations.

302. If Defendants had not routinely disregarded the FDA's cGMPs and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA and NDEA contamination almost immediately.

303. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

304. And as shown above, Defendants' own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

305. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' VCDs would have been discovered in 2012 (or perhaps earlier for other API manufacturers). Defendants were thus on (at minimum) constructive notice that their VCDs were contaminated, adulterated, and/or misbranded as early as 2012.

306. However, there are indications that Defendants had actual knowledge of their VCDs' contamination with NDMA and NDEA, and made efforts to conceal or destroy the evidence.

307. As alleged above, FDA investigators visited ZHP's facilities in May 2017. In the words of FDA inspectors, ZHP "invalidat[ed] [OOS] results [without] scientific justification" and did not implement "appropriate controls … to ensure the integrity of analytical testing," and routinely disregarded sampling anomalies suggestive of impurities.

308. These discoveries by the FDA's investigators suggest that ZHP and Defendants were specifically aware of impurities in the drugs being manufactured by ZHP, including specifically contamination of Defendants' VCDs with NDMA. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce contaminated, adulterated, and/or misbranded VCDs into the U.S. market.

309. Defendants were or should have been aware of ZHP's cGMP violations as early as 2012, if not earlier.

310. Indeed, Defendant Solco and ZHP (as well as Huahai US) are owned by the same corporate parent, ZHP. All of these entities should be imputed with actual knowledge of ZHP's willful deviations from cGMPs because of their corporate affiliations and overlapping operations and employees or agents. For instance, Solco and Huahai US have offices in the same office building in Cranbury, New Jersey.

311. And yet, Defendants knowingly, recklessly, and/or negligently introduced contaminated, adulterated, and/or misbranded VCDs containing dangerous amounts of nitrosamines into the U.S. market. Defendants failed to recall their generic VCDs because they feared permanently ceding market share to competitors. And Defendants issued the "voluntary" recall of their VCDs only after the FDA had threatened an involuntary recall.

L. Other Contaminants

312. Testing and evaluation is ongoing of VCDs manufactured, distributed, or sold by Defendants. Besides NDMA and NDEA, ongoing investigation suggests other impurities, such as NMBA, may exist as well in the VCDs at issue.

M. FDA Announces Voluntary Recall of Defendants' Adulterated and/or Misbranded VCDs

313. On or about July 13, 2018, the FDA announced voluntary recalls by Defendants and other manufacturers for their VCDs manufactured by ZHP.[90] The recall is for products distributed as early as October 2015. However, as alleged above, it is likely that Defendants' VCDs manufactured 2012 and beyond were also contaminated with NDMA and NDEA.

314. On or about July 27, 2018, the FDA announced expanded recalls of additional VCDs manufactured by Defendants and non-parties, and repackaged by third parties.[91]

315. As stated in the FDA's July 13, 2018 statement:

> The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be

[90] FDA, *FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of Impurity* (July 13, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.

[91] FDA, FDA UPDATES ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS INCLUDING VALSARTAN, LOSARTAN AND IRBESARTAN, https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last visited June 5, 2019).

related to changes in the way the active substance was manufactured.

316. Subsequently, the FDA announced numerous additional recalls of VCDs and other similar products manufactured, distributed, or sold by Defendants as well as non-parties.[92] The FDA has not released the results of its investigation into when Hetero, Mylan, and Aurobindo started manufacturing contaminated, adulterated, and/or misbranded VCDs.

N. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic VCDs

317. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their contaminated, adulterated, and/or misbranded VCDs.

1. Warranties Common to All Manufacturer Defendants

318. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[93] The Orange Book is a public document; Defendants sought and received the inclusion of their VCD products in the Orange Book upon approval of their ANDAs. In securing FDA approval to market generic VCDs in the United States

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[92] *Id.*

[93] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last visited June 5, 2019).

as an Orange Book-listed drug, Defendants were required to demonstrate that their generic VCDs was bioequivalent to their RLDs.

319. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

320. Each Defendant's VCD(s) is/are accompanied by an FDA-approved label. By presenting consumers with an FDA-approved VCD label, Defendants, as generic manufacturers, made representations and express or implied warranties to consumers of the "sameness" of their products to the VCD's RLD, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not contaminated, adulterated, and/or misbranded.

321. By introducing their respective VCDs into the United States market as a therapeutic equivalent to their RLDs and with the FDA-approved label that is the same as that of the RLDs, Defendants represent and warrant to end users that their VCDs are in fact the same as and are therapeutically interchangeable with their RLDs. Much of the generic drugs supply chain, including the most critical components of that supply chain (end-user patients) rely on these representations and warranties.

322. In addition, each Defendant affirmatively misrepresented and warranted to consumers through their websites, brochures, and other marketing or informational materials that their VCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

323. The presence of nitrosamines in Defendants' VCDs: (1) renders Defendants' VCDs non-bioequivalent (*i.e.*, not the same) to their RLDs and thus non-therapeutically interchangeable with them, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendants' VCDs non-therapeutically equivalent to their RLDs, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' VCDs containing an ingredient that is not also contained in their RLDs, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, or negligently failed to ensure their VCDs' labels and other advertising or marketing statements accurately conveyed information about their products.

324. The presence of nitrosamines in Defendants' VCDs and Defendants' serial and willful failures to comply with cGMPs and other shortcomings in Defendants' generic drug manufacturing processes have resulted in Defendants'

VCDs being misbranded and adulterated compared to Defendants' representations and warranties.

325. At all relevant times, Defendants have also impliedly warranted that their VCDs were merchantable and fit for their ordinary purposes.

326. Naturally, due to their status as probable human carcinogens as listed by both the IARC and the U.S. EPA, NDMA and NDEA are not FDA-approved ingredients in VCDs. The presence of NDMA and other similar nitrosamines or impurities in Defendants' VCDs means that Defendants have violated implied warranties to Plaintiffs and Class Members. The presence of NDMA or NDEA in Defendants' VCDs results in Defendants' VCDs being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

327. For these and other reasons, Defendants' VCDs are therefore adulterated, misbranded, and/or unapproved, and it was illegal for Defendants' to have introduced such VCDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

328. Adulterated, misbranded, and/or unapproved VCDs contaminated with cancer-causing compounds are essentially worthless. No consumer (including Plaintiffs) would purchase (or reimburse for) these nitrosamine-laden VCDs. In

fact, an adulterated, misbranded, and/or unapproved VCD cannot even be legally sold or purchased within the United States. This is especially so given that alternative, actual VCDs or competing medications with the same approved indications were available from other manufacturers. At a minimum, adulterated, misbranded and/or unapproved VCDs do not possess the same safety and efficacy profile as their branded equivalents. As such, the contaminated VCDs were not what they were supposed to be.

329. Moreover, every consumer who purchased and ingested a contaminated VCD has been exposed to a nitrosamine, a carcinogenic agent with mutagenic properties that operates at the cellular and sub-cellular levels, that caused cellular and genetic injury creating and/or increasing the risk that Plaintiffs will develop cancer.

330. The recalls were meant to quickly remove unsafe products from the market. While FDA advised patients to continue taking VCDs, it only did so as an interim measure because of a potential shortage of the medication and the risks associated with untreated high blood pressure.

331. In response to the recall, pharmacies and health care providers throughout the United States contacted affected patients to advise them of the recall and to recommend that they contact their doctors to request a replacement or an alternative treatment option.

332. Because of the seriousness of the impurity—unsafe levels of a carcinogen— all or virtually all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. VCDs had no use and were discarded.

2. ZHP Defendants' Warranties

333. On its January 29, 2019 website,[94] ZHP stated that it "has established an independent, strict and sound quality mangement [sic] system in accordance with GMP." ZHP further claims that it "ensure[s] that production is operated in accordance with GMP and product quality meets the required specifications," and that ZHP's "workshops of formulation are designed in strict compliance with the international cGMP standard, where the most advanced automatic pharmaceutical production equipment in the world was introduced."

334. Huahai US assisted Prinston in obtaining approval of its ANDA for its VCDs.

335. Prinston lists its valsartan as equivalent to Diovan on its website.[95]

[94] ZHP completely changed its website sometime in February or March 2019.

[95] Prinston, PRODUCT LIST, http://www.prinstonpharm.com/Products_List.html#v (last visited Apr. 5, 2019).

336. Furthermore, Solco states on the "About Solco" page of its website that "[b]y using the same active ingredients, [Solco] produce[s] products which are identical (equivalent) to the branded medication."[96]

337. On the "Drug Safety" page of its website, Solco states that "Solco Healthcare is committed in providing … its patients with high quality, FDA-approved generic medications."[97]

338. Solco lists its valsartan products on its website with the statement that the "Reference Listed Drug" is "Diovan®" along with a link to download Solco's valsartan Prescribing Information.[98]

3. Hetero Defendants' Warranties

339. In touting itself, Hetero claims that it has "over 36 advanced manufacturing facilities strategically located across the world – including India, USA, China, Russia, Egypt, Mexico and Indonesia. Approved by stringent global regulatory authorities, Hetero facilities have integrated quality systems and processes to ensure adherence to cGMP (current Good Manufacturing practices). They are also vertically integrated and can be utilized for large-scale production of

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[96] Solco, OVERVIEW, http://solcohealthcare.com/about-solco.html (last visited Apr. 5, 2019).

[97] Solco, TRADE PARTNER INFORMATION, http://solcohealthcare.com/trade-partner-information.html#DrugSafety (last visited Apr. 5, 2019).

[98] Solco, VALSARTAN TABLETS, http://www.solcohealthcare.com/product/valsartan-tablets#NDC-43547-367-03 (last visited Apr. 5, 2019).

APIs, formulations in various dosage forms rapidly. We make continuous investments in upgradation of manufacturing facilities with special emphasis on deploying advanced machinery and adopting latest technologies to comply with 21 CFR. Besides enabling us consistently produce high quality medicines at an affordable cost, it also helps us in passing through regulatory audits with relative ease. It is these advantages that make us the partner of choice for major global pharmaceutical companies."[99]

340. Indeed, Hetero further describes itself as "a research-driven pharmaceutical company, is committed to the development, manufacturing and marketing of active pharmaceutical ingredients (APIs), intermediates and finished dosages. Today, Hetero is recognized as a world leader in process chemistry, API manufacturing, formulation development, manufacturing and commercialization. Hetero has around 18 state-of-the-art manufacturing facilities, which are cGMP compliant and have been approved by various Ministries of Health and regulatory authorities like US FDA, WHO, MCC - South Africa, MHRA-UK, TGA – Australia, PMDA – Japan, KFDA (Korea) among others. The company has a rich manufacturing product portfolio of over 200 products across a wide range of therapeutic categories. Hetero has a strong global presence in over 120 countries

[99] Hetero, MANUFACTURING CAPABILITIES, https://www.heteroworld.com/manufacturing.php (last visited June 6, 2019).

and has been offering API's and generic formulations to partners across the globe.… Hetero, a privately-owned company, is recognized as one of the top 10 companies in the Indian pharmaceutical industry with an annual turnover of US$ 1.2 billion. With a dedication and support of its 15,000 employees, Hetero continues its commitment to manufacture high-quality drugs and save millions of lives across the world."[100]

341. Specifically, with respect to its manufacturing of API, Hetero purports to be "proficient in achieving regulatory approvals worldwide of both APIs and formulations. With an integrated quality system to ensure adherence to cGMP practices, Hetero is committed to quality and its manufacturing facilities are approved by global regulatory agencies. In addition, Hetero continues to invest in its state-of-the-art manufacturing facilities and capabilities to ensure that it is able to provide the highest level of quality standards in the pharmaceutical industry."[101]

342. Hetero likewise goes to great lengths in describing its products as the same as the brand drug. It states that its generic drugs are "copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

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[100] Camber, OUR PARENT COMPANY: HETERO, http://camberpharma.com/about-us/hetero (last visited June 6, 2019).

[101] Camber, GLOBAL RESOURCES, http://camberpharma.com/global-resources (last visited June 6, 2019).

Health care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs.… Generic drugs look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect the performance, safety or effectiveness of the generic drug. They look different because trademark laws in the U.S. do not allow a generic drug to look exactly like other drugs already on the market.… To find out if there is a generic equivalent for your brand-name drug, visit FDA.gov to view a catalog of FDA-approved drug products, as well as drug labeling. Since there is a lag time after generic products are approved and they appear in the "Orange Book", you should also consult the most recent monthly approvals for "First Generics" at FDA.gov."[102]

343. Camber compares its valsartan to DIOVAN on its website's product catalog.[103]

[102] Camber, ABOUT GENERICS, http://camberpharma.com/generics (last visited June 6, 2019)

[103] Camber, PRODUCT, http://camberpharma.com/products?&filter=V (last visited June 6, 2019).

4. Mylan Defendants' Warranties

344. Mylan has a section of its website discussing generics, and claims that "[g]eneric pharmaceuticals are the same as existing approved brand-name drugs in active ingredient, dosage form, safety, strength, route of administration, quality and performance characteristics. Generic medications are just as safe and effective as their brand-name counterparts, and often cost less." [104]

345. Mylan also guarantees that "consumers can be assured that FDA-approved generic products have met the same rigid manufacturing standards as the innovator drug."

346. According its website as of November 2018, "Mylan offers one of the broadest portfolios of active pharmaceutical ingredients (API)—the ingredients responsible for the therapeutic effects of different medicines—to more than 100 countries. Quality begins at step one. Mylan uses an established testing and verification process to ensure the suitability of active ingredients used in our medicines. Direct access to API makes Mylan one of the few global generics companies with a comprehensive, vertically integrated supply chain and helps us maintain deep insight into diverse markets and therapeutic segments.… With a commitment to quality, state-of-the-art API manufacturing facilities, global

[104] Mylan, GENERICS, https://www.mylan.com/en/products/generics (last visited June 5, 2019).

regulatory accreditations, a strong pipeline and speed-to-market capabilities, Mylan is an ideal API partner."[105]

347. According to Mylan's website, "[b]eing a manufacturer of API makes Mylan one of the few global generics companies with a comprehensive, vertically integrated supply chain" that Mylan touts as "provid[ing] us with an extra measure in the quality process that we can own[.]"[106]

348. Mylan's online product catalog lists its generic VCDs as equivalent to their RLDs.[107]

5. Aurobindo Defendants' Warranties

349. Aurobindo's website states that it is "[c]ommitted to Quality and Safety."[108]

350. On January 6, 2015, Aurobindo announced that it had received FDA approval to manufacture and market valsartan, adding that valsartan is the "the generic equivalent to the reference listed drug product (RLD) Diovan®."

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[105] Mylan changed this part of its website sometime after November 2018.

[106] Mylan, ACTIVE PHARMACEUTICAL INGREDIENTS, https://www.mylan.com/en/products/active-pharmaceutical-ingredients (last accessed June 6, 2019).

[107] Mylan, PRODUCT CATALOG, https://www.mylan.com/en/products/product-catalog/ (last visited June 6, 2019) (clicking on the relevant product shows the page and RLD reference for each VCD).

[108] Aurobindo, HOMEPAGE, https://www.aurobindo.com/ (last visited June 5, 2019).

351. According to Aurobindo USA, "[a]s a truly integrated company, we assure continuity and quality from start to finish."[109] Aurobindo also "[s]eek[s] to attain the highest quality standards."[110]

352. Aurobindo USA's website lists DIOVAN as its valsartan's "Brand Reference."[111]

353. Aurolife states, "[t]he Aurolife family consists of an experienced management team with expertise in manufacturing, R&D, Quality Assurance and Quality control, finance and regulatory affairs. Aurolife has 100,000 square feet state-of-the-art US FDA approved cGMP compliant manufacturing facility with an investment of over US $50 million."[112]

6. Teva Defendants' Warranties

354. Teva has a "Generics FAQs" on its website.[113] In response to the question "Are generic drugs safe?" Teva states the following:

A generic drug is bioequivalent to the original innovative

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[109] Aurobindo USA, AUROCONTROL, https://www.aurobindousa.com/company/our-story/aurocontrol/ (last visited June 5, 2019).

[110] Aurobindo USA, OUR STORY, https://www.aurobindousa.com/company/our-story/ (last visited June 5, 2019).

[111] Aurobindo USA, VALSARTAN TABLETS, https://www.aurobindousa.com/product-category/valsartan-tablets/ (last visited June 5, 2019).

[112] Aurolife, ABOUT AUROLIFE, http://aurolifepharma.com/aboutus.html (last visited June 5, 2019).

[113] Teva, PRODUCTS, http://www.tevapharm.com/our_products/generic_qa/ (last visited June 5, 2019).

> drug and meets the same quality standards. The active ingredient, the content, the dosage form and the usage of a generic drug are similar to those of an innovative drug. Generic drugs are essentially the same as the original drug, but are offered at a lower price.

355. In response to the question "How do you ensure generic drug safety, having tried it in only a limited number of patients?" Teva states the following:

> The generic product's active pharmaceutical ingredient (API) is identical to that of the innovative drug, its purity profile is similar and it is found to be bioequivalent; therefore its safety and efficacy are also comparable.

356. Similarly, under the webpage titled "Uncompromising Quality," Teva states that it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" with through Teva's "impeccable adherence to … [cGMPs][.]"

357. Teva's website states that "Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products."[114]

[114] Teva, COMPANY PROFILE: UNCOMPROMISING QUALITY, https://www.tevapharm.com/about/profile/quality_assurance/ (last visited June 5, 2019).

358. According to Teva, "[o]ur manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals."[115]

359. In a May 16, 2018 catalog of "all Teva and Actavis products," Teva, Actavis, Teva USA, Arrow, and Actavis Pharma all stated that their VCDs were "bioequivalent" to their RLDs.

360. Teva USA's website states, "Teva's commitment to quality is uncompromising and we manufacture according to the highest quality and compliance standards. This focus is evident at every stage of the development and production of our medicines. All of our manufacturing processes are validated and products are tested and certified, using state-of-the-art testing equipment throughout the manufacturing process designed to ensure adherence to the highest quality and compliance standards."[116]

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[115] *Id.*

[116] Teva USA, ABOUT TEVA: QUALITY YOU CAN TRUST, https://www.tevausa.com/About-Teva/article-pages/quality/ (last visited June 5, 2019).

361. Teva USA's Code of Conduct affirms, "To ensure we are in compliance and working in accordance with sound quality principles in our research laboratories, in our clinical trials, and in our manufacturing plants and distribution centers, we adhere to the systems and internal controls for 'Good Operating Practices,' or 'GxP,' including Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) Good Pharmacovigilance Practices (GVP) and Good Distribution Practices (GDP)."[117]

362. Teva USA maintains a Brand-to-Generic Medication Reference on its website.[118] Before its recall of VCDs, this Reference included VCDs and their RLD equivalents.

7. Torrent Defendants' Warranties

363. Torrent Pharmaceutical's website states that they, "strongly believe in providing quality medicines at affordable price to the patients. In this quest, primarily, we have inclined ourselves towards safeguarding both the qualitative and quantitative aspects with the help of our robust manufacturing technologies and manufacturing facilities."[119]

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[117] Teva USA, TEVA CODE OF CONDUCT, https://www.tevausa.com/About-Teva/article-pages/Code-of-Conduct/ (last visited June 5, 2019).
[118] Teva USA. PATIENTS: RESOURCES, https://www.tevagenerics.com/patients/resources/ (last visited June 5, 2019).
[119] Torrent Pharmaceuticals, MANUFACTURING, http://www.torrentpharma.com/Index.php/site/info/manufacturing (last visited June 5, 2019).

8. Warranties Common to All Retail Pharmacy Defendants

364. Retail pharmacies are where consumers purchase and fill prescriptions for pharmaceuticals. As a result, retail pharmacies and consumers have direct privity of contract. With each sale of prescription drugs, retail pharmacies impliedly warrant to consumers that the prescription drugs being sold to them are merchantable and/or fit for its ordinary uses.

365. By selling pharmaceutical prescription drugs in the stream of commerce, each retail pharmacy defendant warrants that the generic drugs for which they receive payments are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. More generally, retail pharmacy defendants warrant that prescription drugs they sell are of a standard quality.

366. On account of the existence of these strict liability implied warranties, most retail pharmacies secure indemnification from manufacturer defendants for breach of such warranties.

367. Further, each retail pharmacy defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including contaminated, adulterated, and/or misbranded) drugs.

9. Wholesale Distributor Defendants' Warranties

368. Each distributor defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including contaminated, adulterated, and/or misbranded) drugs.

a. Cardinal Defendants' Warranties

369. Cardinal's Standards of Business Conduct state, "We have quality systems in place to ensure that we manufacture, handle, store and distribute products in accordance with applicable legal and regulatory requirements. Every employee is responsible for following our quality processes when working with the products we sell."[120] The Standards also require Cardinal to "[u]nderstand and comply with the policies that cover the manufacture, storage, handling and distribution of products we sell."[121]

370. Harvard also follows Cardinal's Standards.[122]

371. Harvard describes its valsartan as DIOVAN on its website.[123]

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[120] Cardinal, STANDARDS OF BUSINESS CONDUCT, https://www.cardinalhealth.com/content/dam/corp/web/documents/fact-sheet/cardinal-health-standards-of-business-conduct-booklet-english.pdf (last visited Apr. 5, 2019).

[121] *Id.*

[122] Harvard, COMPLIANCE, https://www.theharvarddruggroup.com/compliance/ (last visited Apr. 5, 2019).

[123] Harvard, SEARCH RESULTS FOR VALSARTAN, https://www.theharvarddruggroup.com/shop/item/get-list/type/search?term=valsartan (last visited June 5, 2019).

372. Major's June 2018 Product Catalog compared its valsartan to DIOVAN.[124]

373. Major "also maintain[s] strong relationships with generic manufacturers and suppliers who we routinely audit to ensure compliance with our standards."[125]

374. Major follows Cardinal's Standards of Business Conduct.[126]

b. McKesson Defendants' Warranties

375. McKesson's Code of Conduct provides that it only does "business fairly and with integrity."[127] McKesson touts that it "compl[ies] with applicable laws everywhere we do business around the world," and requires action by the company when it is "aware of (or even suspect[s]) illegal or unethical behavior or violations of the Code, other local policies or applicable laws."

c. AmerisourceBergen Defendants' Warranties

376. AmerisourceBergen's Code of Ethics and Business Conduct states that the company shall engage in "fair dealing" and will not "take unfair advantage

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[124] Major removed valsartan from its current catalog. See Major, FEBRUARY 2019 PRODUCT CATALOG, https://www.majorpharmaceuticals.com/wp-content/uploads/Product-Catalog.pdf (last visited June 5, 2019).

[125] Major, MAJOR® RX SOLUTIONS, https://www.majorpharmaceuticals.com/rx-solutions/ (last visited June 5, 2019).

[126] Major, COMPLIANCE, https://www.majorpharmaceuticals.com/compliance/ (last visited June 5, 2019).

[127] McKesson, CODE OF CONDUCT, https://www.mckesson.com/documents/investors/mckesson-code-of-conduct/ (last visited June 5, 2019).

of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair dealing practice."[128]

10. Repackager and Relabeler Defendants' Warranties

377. By selling drugs in the stream of commerce, each repackager and relabeler defendant warrants that the generic drugs they sell are same as existing brand-named drugs in active ingredient, dosage form, safety, strength, routs of administration, quality, and performance characteristics.

378. Further, each repackager and relabeler defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

11. Repackager and Relabeler Defendants' Warranties

379. By selling drugs in the stream of commerce, each repackager and relabeler defendant warrants that the generic drugs they sell are same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics.

380. Further, each repackager and relabeler defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including contaminated, adulterated, and/or misbranded) drugs.

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[128] AmerisourceBergen, CODE OF ETHICS AND BUSINESS CONDUCT, http://investor.amerisourcebergen.com/static-files/469bd747-6c88-405d-a6eb-00a9b82053d8 (last visited June 5, 2019).

O. New Revelations Continue to Unfold About Other Manufacturing Plants

381. The initial recall of Defendants' VCDs was only the tip of the iceberg. Just two weeks after the FDA's initial recall announcement, the FDA issued another announcement expanding the recall to other VCDs manufactured at another plant in India, and by other non-parties. On August 20, 2018 the FDA announced that it was going to test all VCDs for NDMA.[129] Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known. Indeed, grossly inadequate manufacturing processes have been observed in Aurobindo's facility as recently as *one month ago* (May 2019), nearly a year after the recall of the VCDs.

P. Fraudulent Concealment and Tolling

382. Plaintiffs' and Class Members' causes of action accrued, at the earliest, on the date the FDA announced the recall of Defendants' generic VCDs.

383. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge

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[129] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings* (Aug. 30, 2018), http://freepdfhosting.com/1c7e5ed26e.pdf.

of their and other Defendants' cGMP violations with respect to their VCDs, and of the fact that their VCDs were adulterated and/or misbranded and contaminated with nitrosamines, and were not the same as their RLDs.

384. For instance, no Defendant revealed to the public that their VCDs contained nitrosamines or was otherwise contaminated, adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to their RLDs until the FDA's recall announcement in July 2018. The inspection report which preceded the recall announcement was heavily redacted (including the names of the drugs affected by ZHP's cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

385. To the contrary, each Defendant continued to represent and warrant that their generic VCDs were the same as and therapeutically interchangeable with their RLDs.

386. For instance, Huahai US publicly announced on its website that, contrary to the FDA's pronouncements, that no impurity was discovered until June 2018.[130]

387. Because of this, Plaintiffs and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, each

[130] Huahai US, PRESS RELEASE – UPDATE ON VALSARTAN API – A STATEMENT FROM THE COMPANY, https://www.huahaius.com/media.html (last visited June 5, 2019).

Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the purchase and use of their VCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

388. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

V. CLASS ACTION ALLEGATIONS

389. Plaintiffs bring this action on behalf of themselves and, under Federal Rule of Civil Procedure 23(a), (b)(2), (b)(3), and (c)(4), as representatives of the classes defined as follows:

390. All individuals residing in the United States of America and its territories and possessions who consumed generic valsartan-containing drugs contaminated with NDMA, NDEA, or other nitrosamine, manufactured by or for

Defendants and marketed in the United States and its territories and possessions, at least since January 1, 2012, the "Nationwide Class."

391. Excluded from the Nationwide Class, and from the other additional and alternative classes defined below, are Defendants and their subsidiaries and affiliates; all persons who make a timely election to be excluded from the Class or classes to the extent any class is an opt-out class or a hybrid opt-out class; governmental entities; and any judicial officers who preside over this case and their immediate family members. Also excluded from the Nationwide Class are those consumers of VCDs who have been diagnosed with cancers as a result of taking Defendants' NDMA-, NDEA-, or other nitrosamine-contaminated VCDs.

392. Plaintiffs allege additional classes for all individuals in each State, territory, or possession – or combination(s) of States, territories, or possessions to the extent class members from jurisdictions can be grouped together for purposes of class treatment – who, since at least January 1, 2012 to the present, consumed generic valsartan-containing drugs contaminated with NDMA, NDEA, or other nitrosamine, manufactured by or for Defendants and marketed in the United States and its territories and possessions. These include but are not limited to the following:

a. Plaintiff Judson seeks to represent a California class or class(es) of states with similar applicable laws to California.

b. Plaintiff Zehr seeks to represent a Florida class or class(es) of states with similar applicable laws to Florida.

c. Plaintiffs Kruk and Rives seek to represent an Illinois class or class(es) of states with similar applicable laws to Illinois.

d. Plaintiffs Fields and Daring seek to represent a Maryland class or class(es) of states with similar applicable laws to Maryland.

e. Plaintiff Silberman seeks to represent a New Jersey class or class(es) of states with similar applicable laws to New Jersey.

f. Plaintiff Rodich-Annese seeks to represent a Pennsylvania class or class(es) of states with similar applicable laws to Pennsylvania.

g. Plaintiffs Roger and Judy Tasker seek to represent a West Virginia class or class(es) of states with similar applicable laws to West Virginia.

393. Collectively, the foregoing Nationwide Class and its alternative classes and are referred to as the "Class."

394. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or create subclasses, in light of future fact discovery, and including as the Court deems necessary. These may include, by way of example, bellwether classes or state or other sub-classes.

A. The Classes Meet the Rule 23 Requirements

386. Plaintiffs meet the prerequisites of Rule 23(a), (b), and (c) to bring this action on behalf of the Class and Classes.

387. **Numerosity (Rule 23 (a)(1))**: While the exact number of Class Members cannot be determined without discovery, the proposed nationwide class potentially reaches the millions, and there is no proposed class with fewer than thousands or more of members. The Class Members are therefore so numerous that joinder of all members is impracticable as to the nationwide class and/or as to the subclasses.

388. **Commonality (Rule 23(a)(2))**: Even a single common question can drive a litigation and warrant certification. Here, material common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant's VCDs were contaminated with NDMA or NDEA and thus contaminated, adulterated, and/or misbranded;

b. Whether Defendants violated cGMPs regarding the manufacture of their VCDs;

c. Whether Defendants negligently or defectively manufactured the VCDs consumed by Plaintiffs and other Class Members;

d. Whether Defendants misrepresented facts or failed to warn as to the contamination;

e. Whether each Defendant made and breached express or implied warranties of "sameness" to Plaintiff and other Class Members regarding their generic VCDs, representing they were the same as their RLDs;

f. Whether each Defendant affirmatively misrepresented that its VCDS were the same as their RLDs and thus therapeutically interchangeable, or omitted the fact that it was not;

g. Whether each Defendant affirmatively misrepresented that it was compliant with cGMPs, or omitted the fact that it was not;

h. Whether Plaintiffs and other Class Members have suffered cellular and/or genetic injury and are at increased risk of developing cancer as a result of each Defendant's unlawful conduct;

i. Whether testing is available for the cancers to which Plaintiffs and the Class Members are at increased risk;

j. The nature and extent of medical monitoring, testing, examinations, and treatment necessary to address the risks created by Plaintiffs and other Class Members' consumption of VCDs contaminated with NDMA or NDEA;

k. When Plaintiffs' and other Class Members' claims for relief accrued;

l. Whether Defendants fraudulently concealed Plaintiff's and other Class Members' causes of action.

389. **Typicality (Rule 23(a)(3))**: Plaintiff's claims are typical of Class Members' claims. Plaintiff and other Class Members all suffered the same type of harm, including exposure to NDMA and/or NDEA, cellular and/or genetic injury, cancer, and/or an increased risk of developing cancer, but have not yet been diagnosed with cancer. Plaintiffs bring claims under the same legal and remedial theories as the class. Plaintiffs' claims arise out of the same set of facts and conduct as all other Class Members.

390. **Adequacy of Representation (Rule 23(a)(4) and Rule(g))**: Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in pharmaceutical and products liability litigation, medical monitoring, consumer litigation, and class actions. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members and Plaintiffs will fairly and adequately represent the interests of Class Members

391. **Rule 23(b)(2):** Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Classes as a whole.

392. **Rule 23(b)(3) Predominance and Superiority:** Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. The likelihood that individual Class Members will prosecute separate actions for medical monitoring is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical and product liability litigation, consumer litigation, class actions, and federal court litigation, foresee the efficient management of this case as a class action.

393. **Rule 23(c)(4) Issues Class:** To the extent the Court determines there are material differences in the relevant laws and that such differences present class manageability issues precluding nationwide class certification for all purposes, Plaintiffs submit that a nationwide issue class is appropriate for determination of common material fact issues in the case, and are predicates for the entitlement to

medical monitoring (such as exposure, contamination, misconduct, increased risk, existence of testing and benefit of testing, among others).

VI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

NEGLIGENCE
(Individually and on Behalf of the Class)

394. Plaintiffs repeat and re-allege the preceding paragraphs as if fully set forth herein.

395. Each Defendant owed a duty to Plaintiffs and the Classes to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of its VCDs.

396. Each Defendant owed a duty to Plaintiffs and the Classes to ensure that the VCDs it sold in the United States were not contaminated with NDMA or NDEA, contained only the ingredients stated in the label, were therapeutically equivalent to brand Diovan, and/or complied with cGMPs, and/or was not contaminated or adulterated.

397. Each Defendant owed a duty of care to Plaintiffs and the Classes because they were the foreseeable, reasonable, and probable users of VCDs. Each Defendant knew, or should have known, that its Valsartan product was contaminated with NDMA and/or NDEA, did not contain only the ingredients stated, was not therapeutically equivalent to brand Diovan and/or did not comply

with cGMPs, and/or were adulterated, and each was in the best position to uncover and remedy these shortcomings.

398. Defendants negligently manufactured the Valsartan at issue, causing contamination with NDMA and NDEA, which are carcinogens.

399. Each Defendant failed to fulfill its duty of care. Each Defendant inadequately conducted or oversaw the manufacture, testing, labeling, distribution, marketing, warnings, disclosures, and sale of the Valsartan at issue. Each Defendant knew that the aforesaid wrongdoing would damage Plaintiffs and other Class Members.

400. Each Defendant negligently failed to promptly and immediately warn and disclose to Plaintiffs and other Class Members, and the medical and regulatory communities, of the potential and actual contamination with NDMA and/or NDEA as soon as it was discovered, delaying notice of this harmful and potentially fatal toxic exposure to a carcinogen and thus causing continued exposure to the carcinogenic contamination, and delaying necessary testing, examinations, surveillance, and treatment.

401. Defendants' negligent conduct created and then exacerbated an unreasonable, dangerous condition for Plaintiffs and other Class Members.

402. Defendants acted with recklessness and willful and wanton disregard for the health of Plaintiffs and other Class Members.

403. Each Defendant's own unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiffs and other Class Members and created a foreseeable risk of harm to Plaintiff and other Class Members.

404. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and other Class Members have suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

405. Plaintiffs and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment,

attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SECOND CLAIM FOR RELIEF

NEGLIGENCE PER SE
(Individually and on Behalf of the Class)

406. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

407. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its VCDs.

408. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the VCDs it sold in the United States were therapeutically equivalent to brand Diovan and complied with cGMPs and were not adulterated or misbranded.

409. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards.

410. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

411. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

412. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and other Class Members have suffered cellular and genetic

injury which creates and/or increases the risk that Plaintiffs will develop cancer, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

413. Plaintiffs and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just..

THIRD CLAIM FOR RELIEF

MEDICAL MONITORING
(Individually and on Behalf of the Class)

414. Plaintiffs repeat and re-allege the preceding paragraphs as if fully set forth herein.

415. As a proximate result of Defendants' acts and omissions, the Class is at an increased risk of developing cancer above the normal base-level risk.

416. As alleged above, Defendant's Valsartan product was contaminated with NDMA/NDEA, an agent known to cause cancer in humans.

417. The Class Members may not develop cancer for many years.

418. The Class Members are at an increased risk as they consumed and/or ingested Defendants' VCDs for extended periods of time, some as many as several years, and as a result were exposed to a contaminant.

419. Upon information and belief, and based upon the internal and external investigations now made public, the Class is at an increased risk as they were exposed to NDMA/NDEA.

420. NDMA/NDEA is a hazardous, life-threatening, toxic substance that is known to cause cancer in humans.

421. The Class Members are at an increased risk of cancer as they were exposed to, consumed, and/or ingested Defendants' VCDs in quantities, and over periods of time sufficient to establish an exposure level that is considered to be hazardous to health, and that is considered to be sufficient to cause cancer or increase the risk of developing cancer.

422. The exposure was caused solely and proximately by Defendants' failure to adequately manufacture their VCDs to be therapeutically equivalent to

brand Diovan; their failure to address discrepancies in batches/doses of Valsartan during quality control testing; their material misrepresentations, false statements, and other deceptive practices in continuing to claim that their Valsartan product was safe for consumption and/or ingestion and therapeutically equivalent to Diovan.

423. Defendants had a duty to the Class Members to: ensure and warrant that their Valsartan product was indeed therapeutically equivalent to brand Diovan as claimed and advertised to the Class Members; to disclose to the Class Members any defect, contamination, impurity or other potential health hazard known or discoverable by Defendants; and to ensure that their Valsartan product was not safe, reliable, and non-hazardous for human consumption—its intended purpose.

424. As alleged above, Defendants' own negligent acts and omissions resulted in cancer, or an increased risk of developing cancer for all members of the Class. Cancer is a serious disease-causing life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, test and/or monitoring procedures exist and are readily available to provide for the testing and early detection of cancer in patients. These technologies, tools tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. These existing scientific methods include, but are not limited to, guaiac-based fecal occult blood test (gFOBT), fecal immunochemical test (FIT),

FIT-DNA test, Flexible Sigmoidoscopy, Colonoscopy, and CT Colonography (Virtual Colonoscopy).

425. Early detection of cancer in patients is one of the best, and sometimes the only means to treat cancer such that it does not cause lasting, permanent injury, illness, or death.

426. Early detection of cancer in patients necessarily allows patients to avail themselves of myriad forms of treatment, each of which is capable to altering the course of the illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate injury.

427. The tests and treatments for the early detection and treatment of cancer must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because NDMA/NDEA -associated cancer screenings may not be conducted with the frequency necessary to identify cancer in the absence of exposure to NDMA/NDEA, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require more frequent screenings not within the purview of routine medical exams.

428. The facts alleged above are sufficient or more than sufficient to plead a claim for medical monitoring as a cause of action.

429. Plaintiffs seek, on behalf of themselves and the Class Members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FOURTH CLAIM FOR RELIEF

PRODUCTS LIABILITY-MANUFACTURING DEFECT (Individually and on Behalf of the Class)

430. Plaintiffs repeat and re-allege the preceding paragraphs as is fully set forth herein.

431. The Valsartan at issue was defectively manufactured, as the manufacturing process caused contamination of the Valsartan with NDMA and NDEA.

432. Valsartan contaminated with NDMA and/or NDEA is by definition defectively manufactured.

433. Defendants' conduct in defectively manufacturing Valsartan was reckless and taken with wanton and willful disregard for the health of Plaintiffs and other Class Members.

434. Defendants are strictly liable for the harm caused by or contributed to by the defectively manufactured Valsartan.

435. As a direct and proximate result, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' VCDs they consumed were contaminated with NDMA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

436. Plaintiffs seek, on behalf of themselves and the Class Members, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical

consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FIFTH CLAIM FOR RELIEF

FAILURE TO WARN
(Individually and on Behalf of the Class)

437. Plaintiffs repeat and re-allege the preceding paragraphs as is fully set forth herein.

438. Defendants failed to warn Plaintiffs and the Class Members, and the medical and regulatory communities, of the potential or actual contamination of the Valsartan with NDMA and NDEA, as soon as this was suspected or known.

439. Defendants' failure to warn was intentional, reckless, and in wanton and willful disregard for the rights and health of Plaintiffs and other Class Members, causing exposure to carcinogens and delay of diagnosis and treatment.

440. Defendants are strictly liable for their failure to warn or adequately disclose information.

441. As a direct and proximate result of each Defendant's failure to warn or disclose information, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' VCDs they consumed were contaminated

with NDMA or NDEA and thus created and/or increased the risk that Plaintiffs and other Class members will develop cancer.

442. Plaintiffs seek, on behalf of themselves and the Class Members, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SIXTH CLAIM FOR RELIEF

VIOLATION OF THE MAGNUSSON-MOSS WARRANTY ACT 15 U.S.C. § 2301 *et seq.* (Individually and on Behalf of the Class)

443. Plaintiffs repeat and re-allege the preceding paragraphs as is fully set forth herein.

444. Plaintiffs bring this Count on behalf of members of the Classes who are residents of the following States: Alaska, Arkansas, California, Colorado, Delaware, District of Columbia, Hawaii, Indiana, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, West Virginia and Wyoming.

445. This Court has jurisdiction to decide claims brought under 15 U.S.C. § 2301 by virtue of 28 U.S.C. § 1332 (a)-(d).

446. The contaminated doses of Valsartan are "consumer products" within the meaning of the Magnusson-Moss Warranty Act, 15 U.S.C. § 2301(1).

447. Plaintiffs are "consumers" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3). They are consumers because they are persons entitled under applicable state law to enforce against the warrantor the obligations of its express and implied warranties.

448. Defendants were "supplier[s]" and "warrantor[s]" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(4)-(5).

449. 15 U.S.C. § 2310(d)(1) provides a cause of action for any consumer who is damaged by the failure of a warrantor to comply with a written or implied warranty.

450. Defendants provided Plaintiffs and the other Class members with an implied warranty of merchantability in connection with the purchase of Valsartan that is an "implied warranty" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(7). As a part of the implied warranty of merchantability, Defendants warranted that the Valsartan ultimately found to be contaminated with NDMA and/or NDEA was fit for its ordinary purpose as a safe pharmaceutical medication, would pass without objection in the trade as designed, manufactured, and marketed, and were adequately contained, packaged, and labeled. N.J. Stat. Ann. § 12A:2-314(2)(a), (c), and (e); U.C.C. § 2-314.

451. Defendants breached these implied warranties, as described in more detail above, and are therefore liable to Plaintiffs and the Class pursuant to 15 U.S.C. § 2310(d)(1). Without limitation, doses and/or batches of contaminated Valsartan share common design defects in that they have caused cellular and/or genetic injury, cancer, or an increased risk of developing cancer.

452. In their capacity as warrantors, Defendants had knowledge of the defects in the batches of Valsartan they manufactured, distributed, and sold, any efforts to limit the implied warranties in a manner that would exclude coverage of contaminated Valsartan is unconscionable, and any such effort to disclaim, or otherwise limit, liability for contaminated Valsartan is null and void.

453. Privity is not required here because Plaintiffs and each of the other Class members are intended third-party beneficiaries of any contracts between Defendants and their distributors, and specifically, of the implied warranties. The distributors were not intended to be the ultimate consumers of Valsartan and have no rights under the warranty agreements provided with each container of Valsartan; the warranty agreements were designed for and intended to benefit consumers. Finally, privity is also not required because the contaminated batches and/or doses of Valsartan are dangerous instrumentalities due to the aforementioned defects and nonconformities. In the alternative, to the extent it is required, it is satisfied.

454. Pursuant to 15 U.S.C. § 2310(e), Plaintiffs are entitled to bring this class action and are not required to give Defendants notice and an opportunity to cure until such time as the Court determines the representative capacity of Plaintiffs pursuant to Rule 23 of the Federal Rules of Civil Procedure.

455. Furthermore, affording Defendants an opportunity to cure their breach of written warranties would be unnecessary and futile here. At the time of sale of each batch and/or dose of contaminated Valsartan Defendants knew, should have known, or were reckless in not knowing of their misrepresentations concerning Valsartan's contamination and failure to perform as warranted, but nonetheless failed to rectify the situation and/or disclose the contamination.

456. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SEVENTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (Individually and on Behalf of the Class)

457. Plaintiffs repeat and re-allege the preceding paragraphs as if fully set forth herein.

458. Defendants are merchants with respect to Valsartan within the laws of each jurisdiction.

459. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial

Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841*, et seq.*; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

460. Each Defendant was a merchant within the meaning of the above statutes.

461. Each Defendant's Valsartan product constituted "goods" or the equivalent within the meaning of the above statutes.

462. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit VCDs for the purpose for which the products were sold, and to conform to the standards of the trade in which Defendants are involved such that the products were not contaminated with a carcinogen and were of fit and merchantable quality.

463. Each Defendant knew or should have known that its VCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to brand Diovan (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their VCDs were of merchantable quality and fit for that purpose.

464. Each Defendant breached its implied warranty because each Defendant's VCDs were contaminated with a carcinogen and not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

465. Defendants were provided notice of these issues by numerous discrepancies in quality control testing results, evidence of contaminants in

analyses of batches/doses of Valsartan, investigations conducted internally and by the FDA and communications sent by the Class before or within a reasonable amount of time after Defendants

466. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' VCDs they consumed were contaminated with NDMA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

467. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

EIGHTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTIES
(Individually and on Behalf of the Class)

468. Plaintiffs repeat and re-allege the preceding paragraphs as if fully set forth herein.

469. Each Defendant expressly warranted that its VCDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

470. Each Defendant sold VCDs that they expressly warranted were compliant with cGMP and/or not adulterated and/or misbranded.

471. Each Defendant's VCDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated and/or misbranded.

472. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat.

§ 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

473. At the time that each Defendant marketed and sold its VCDs, it recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, and cGMP compliant and/or not adulterated and/or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members, including but not limited to express representations made in referring to

their VCDs as valsartan, valsartan HCT, amlodipine-valsartan, and and/or amlodipine-valsartan HCT.

474. Each Defendant breached its express warranties with respect to its VCDs as it was contaminated and not of merchantable quality, was not fit for its ordinary purpose, and did not comply with cGMP and/or was adulterated and/or misbranded.

475. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that the Defendants' VCDs they consumed were contaminated with NDMA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

476. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for

diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

NINTH CLAIM FOR RELIEF

FRAUD/FRAUDULENT CONCEALMENT (Individually and on Behalf of the Class)

477. Plaintiffs repeat and re-allege the preceding paragraphs as is fully set forth herein.

478. This claim is brought on behalf of the Nationwide Class or, alternatively, under the laws of the all states, as there is no material difference in the law of fraud and fraudulent concealment as applied to the claims and questions in this case.

479. Defendants each concealed and suppressed material facts concerning the batches/doses of Valsartan they manufactured, distributed, and sold, that were later found to be contaminated with NDMA/NDEA.

480. As described above, Defendants each made material omissions and affirmative misrepresentations regarding the batches/doses of Valsartan they manufactured, distributed, and sold.

481. The Defendants each knew these representations were false when made.

482. Valsartan purchased by Plaintiffs was, in fact, contaminated, hazardous, a health hazard, unsafe and unreliable, because the Valsartan manufactured by Defendants had not been properly manufactured nor properly tested for quality, and was later found to be contaminated with known carcinogen NDMA/NDEA.

483. The Defendants each had a duty to disclose that the Valsartan they manufactured, distributed, and sold, had been contaminated with NDMA/NDEA, had demonstrated such contamination and other analytical discrepancies when it underwent quality control, and that consequent to that contamination, those batches/doses of Valsartan were potentially hazardous to the Class Members' health and was unsafe for human consumption or ingestion. Plaintiffs relied on Defendants' representations that the Valsartan they were purchasing and ingesting was safe and free from contamination.

484. The aforementioned concealment was material, because if it had been disclosed Plaintiffs would not have purchased or otherwise obtained Valsartan from Defendants.

485. The aforementioned representations were also material because they were facts that would typically be relied on by a person purchasing or obtaining Valsartan. The Defendants each knew or recklessly disregarded that their representations were false because they knew that the Valsartan they were

manufacturing, distributing, and selling was contaminated with NDMA/NDEA, a substance known to cause cancer and/or increase the risk of cancer. The Defendants each intentionally made the false statements in order to sell Valsartan and avoid the expense and public relations nightmare of a recall.

486. Plaintiffs relied on the Defendants' reputation, along with their failure to disclose the contamination of Valsartan and manufacturing and quality control problems, and the Defendants' affirmative assurances that their Valsartan was safe for human consumption and/or ingestion.

487. However, Defendants each concealed and suppressed material facts concerning obligations to monitor and test their products.

488. Further, Defendants each had a duty to disclose the true facts about the contaminated Valsartan because they were known and/or accessible only to Defendants who had superior knowledge and access to the facts, and the facts were not known to or reasonably discoverable by Plaintiffs and the Classes.

489. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' VCDs they consumed were contaminated with NDMA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

490. As a result of the fraud, Plaintiffs have suffered direct and consequential damages, and they seek recovery of those damages, and the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

1. Certifying this Action as a class action;

2. Appointing Plaintiff(s) as Class Representative(s), and appointing undersigned counsel as Class Counsel to represent the Class;

3. A finding that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

4. Awarding appropriate preliminary and/or final injunctive relief;

5. Directing the Defendants to fund medical monitoring in an amount sufficient to fund necessary notice and medical care, including but not limited to examinations, tests, pathology, blood tests, evaluations, and treatment, as necessary and appropriate;

6. Payment to Plaintiff and other Class Members of compensatory damages necessary for their monitoring and care;

7. An award of attorneys' fees and costs;

8. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest; and

9. Such other and further relief as this Court may deem equitable and just.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: June 17, 2019

Respectfully Submitted,

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